

United States Department of Justice

United States Attorney Northern District of Ohio

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July 25, 2018

Enu Mainigi, Esq. Williams & Connolly LLP 725 Twelfth Street, N.W. Washington, DC 20005-5901 emainigi@wc.com

Re: In Re: National Prescription Opiate Litigation.

N.D. Ohio Case No. 1:17-MD-2804

Dear Ms. Mainigi:

The United States Department of Justice ("DOJ") received the attached July 10, 2017 letter, in which you request disclosure of official DOJ information. (Ex. 1.) Specifically, you ask the United States Drug Enforcement Administration ("DEA") to provide 22 years of documents in 37 different categories; the deposition testimony of 15 current and former DEA employees; and Federal Rule of Civil Procedure 30(b)(6) testimony on 24 topics. *Id*.

As you are aware, federal regulations govern the disclosure of official DOJ information by federal employees and agencies, including the DEA. 28 C.F.R. § 16.21-.29. The regulations apply when, as here, the United States is not a party to the proceeding. Under those regulations, current and former DEA employees are prohibited from disclosing official information absent express authorization from the DOJ. 28 C.F.R. § 16.22(a). The Supreme Court has long recognized the authority of federal agencies to regulate the disclosure of information by their employees. In *United States ex rel. Touhy v. Ragen*, the Supreme Court held that a federal employee could not be held in contempt for refusing to produce subpoenaed documents, where his refusal was based on regulations prohibiting the disclosure of official information without prior authorization. 340 US. 462, 468 (1951). Nor did such regulations invade the courts' authority to determine the admissibility of evidence. *Id.* at 468-70.

The *Touhy* regulations are a condition precedent to obtaining testimony or other information from a current or former DOJ employee, and the requesting party must comply with the regulations before DOJ or DEA may respond to any such request. *See Smith v. Cromer*, 159 F.3d 875, 879-80 (4th Cir. 1998); *United States v. Wallace*, 32 F.3d 921 (5th Cir. 1994); *United States*

GOVERNMENT EXHIBIT A v. Bizzard, 674 F.2d 1382 (11th Cir. 1982). The government has a "legitimate interest in orderly governmental operations and the proper use of officials' time." Alex v. Jasper Wyman & Son, 115 F.R.D. 156, 157 (D. Me. 1986). These concerns are especially significant given a request for live testimony from a federal agency. In the face of a request for deposition, "an agency's choice of whether or not to comply with a third-party subpoena is essentially a policy decision about the best use of the agency's resources." Puerto Rico v. United States, 490 F.3d 50, 61 (1st Cir. 2007). Once an agency determines not to provide testimony "in the context of private litigation when the government is not a party, a court should not order testimony to be given . . . without the showing of a compelling interest." Alex, 115 F.R.D. at 157; COMSAT Corp. v. Nat'l Science Found, 190 F.3d 269, 278 (4th Cir. 1999) (to conserve agency resources and prevent a non-party agency from becoming embroiled in private litigation, the decision to permit employee testimony is committed to the agency's sole discretion).

Pursuant to 28 C.F.R. § 16.22, I am the official responsible for consulting with the DEA and authorizing any disclosure in response to your request. Federal regulations require me to consider whether disclosure is appropriate under the applicable rules of procedure and law concerning privilege. 28 C.F.R. § 16.26(a). I cannot release official information if disclosure would:

- 1. Violate a specific statute or regulation;
- 2. Reveal classified information;
- 3. Reveal a confidential source or informant;
- 4. Reveal investigative techniques or investigatory records compiled for law enforcement purposes; or
- 5. Reveal trade secrets without the owner's consent.

28 C.F.R. § 16.26(b).

After carefully considering your request, consulting with the DEA, applying all of the above factors, and reviewing the relevant procedural and substantive law, I have determined that your requests are not appropriate under the procedural rules governing the case. Further, I find that releasing the requested information would not be appropriate under the law concerning privilege; nor would it be appropriate under 28 C.F. R. § 16.26(b).

1. Failure to Comply with Fed. R. Civ. P. 45

A *Touhy* request must be in the form of "a subpoena, order or other demand . . . of a court or other authority." 28 C.F.R. § 16.21(a)(2). As your letter states, you "have not affected formal service of process." (Ex. 1 at 1.) Because your request includes subpoenas to persons no longer employed by the United States, the United States cannot waive service of process on their behalf and requests that all of your subpoenas comply with Rule 45, as well as the *Touhy* regulations.

2. Failure to Provide a Summary of Testimony

Your request fails to provide a summary of the testimony or information sought. A *Touhy* request must include "a statement by the party seeking the testimony or by his attorney, setting forth a summary of the testimony sought." 28 C.F.R. § 16.22(c); see also § 16.22(d). This statement is

necessary to enable me to properly consider the propriety of the request and any applicable privileges or other prohibitions on disclosure. The statement also defines the scope of any authorized testimony. *Id.* § 16.22(c) ("Any authorization for testimony shall be limited to the scope of the demand as summarized in each statement."). I cannot properly make that assessment without a clear request from Defendants.

Your letter seeks a broad and non-exhaustive list of topics you wish to cover at deposition, as evidenced by your use of the phrase "relating but not limited to" before your list of requested topics for each witness. Further, your list of topics is not limited in time or to a particular case. Your letter simply does not provide a reasonably specific summary that would allow me to determine the propriety of the request, whether any privileges apply, and the scope of any authorized testimony.

3. Failure to Provide Statement of Relevance

Your request fails to detail why much of the information you seek is relevant to your defenses in the litigation. A *Touhy* request must also include an explanation of the requested information's "relevance to the proceeding." 28 C.F.R. § 16.22(c); *see also* § 16.22(d). While you assert that the official information "is crucial to Defendants' ability to defend against Plaintiffs' allegations," you have not explained how the requested information is relevant to your defenses. For example, you seek testimony and documents on DEA's recent decision to allow or not allow access to ARCOS data. It is hard to see how such information is relevant to the claims or defenses in the underlying litigation between the parties.

4. Overly Broad and Unduly Burdensome

Your deposition and document requests are overly broad and unduly burdensome in violation of Rules 26 and 45. Compliance with your requests for 30(b)(6) testimony on 24 topics and DEA documents in 37 separate categories would be unduly burdensome to the DEA because of the time it would take for DEA staff to locate, copy, review, and redact this exceptionally large volume of documents. This would disrupt the DEA's mission to prevent the diversion of controlled substances, because Diversion Control Division staff would be assigned to the task. As you know, the DEA is not a party to this litigation, yet it has already spent a great deal of time and resources producing documents at the cost of great time and expense.

Courts routinely protect non-parties from the undue burden of discovery. See Cusumano v. Microsoft Corp., 162 F.3d 708, 717 (1st Cir. 1998) ("Although discovery is by definition invasive, parties to a lawsuit must accept its travails as a natural concomitant of modern civil litigation. Non-parties have a different set of expectations. Accordingly, concern for the unwanted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs."); Sahu v. Union Carbide Corp., 262 F.R.D. 308, 317 (S.D.N.Y. 2009) (stating courts more sensitive to discovery burdens on third parties).

Your deposition requests are unduly burdensome for the additional reason that depositions are usually the most burdensome means of obtaining facts in litigation, and a court may require that information be sought by means that are "more convenient, less burdensome, or less expensive."

See Fed. R. Civ. P. 26(b)(2)(C). Indeed, "[c]ourts generally refuse to compel the deposition of a government witness if the [requesting party] may obtain discovery by an alternative and less burdensome method to the government." See, e.g., Gomez v. City of Nashua, N.H., 126 F.R.D. 432, 436 (D. N.H. 1989). You have not, however, explained why you need depositions here.

Your deposition requests are not only burdensome due to the list of numerous broad topics, but also because they seek testimony under Rule 30(b)(6), thus requiring DEA to prepare witnesses on each of the 24 topics listed. See Infinity Fluids, Corp. v. Gen. Dynamics Land Sys., Inc., No. CV 14-40089-TSH, 2015 WL 4498069, at *2 (D. Mass. July 23, 2015) ("It is . . . unquestionably more burdensome to testify at a Rule 30(b)(6) deposition than an individual deposition, because the designee must educate himself on various matters that may not have been part of what he knows from his own experience."). Moreover, because no one agency employee could possibly have knowledge of all 24 topics on which you seek testimony, your requests effectively seek multiple corporate deponents from the DEA, with the resulting expenditure of substantial time and resources to prepare them for 30(b)(6) depositions. Compliance with your essentially limitless request for testimony would have an adverse impact on government employees in the performance of their mission and duties. See 28 C.F.R. § 16.26.

5. Failure to Describe 30(b)(6) Topics with Reasonable Particularity

For many of the same reasons that your request is overly broad, it also fails to describe the topics of the proposed depositions with "reasonable particularity" as required by Rule 30(b)(6) (a subpoena to a governmental agency "must describe with reasonable particularity the matters for examination."). This "particularity" is necessary to permit appropriate preparation of the witness. Your letter essentially covers every report, investigation, communication, and action by DEA for the last thirty years. This does not comply with Rule 30(b)(6).

6. Unreasonably Cumulative and Duplicative

Your requests are "unreasonably cumulative [and] duplicative" under Rule 26(b), which sets forth the scope and limits of discovery in federal court. Courts limit the "frequency or extent of discovery" if they determine that "the discovery sought is unreasonably cumulative or duplicative." Fed. R. Civ. P. 26(b)(2)(C). Several of your requests are unreasonably cumulative or duplicative because they seek the same testimony from multiple sources. For example, you have listed "DEA's interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74," as a topic for eight (8) different named fact witnesses and one (1) witness pursuant to Fed. R. Civ. P. 30(b)(6).

7. Seeks Law-Enforcement-Sensitive Information

Many of the documents that you seek are protected from disclosure by DOJ's regulations because they are law enforcement sensitive. Pursuant to 28 C.F.R. § 16.26(b)(5), the DEA is prohibited from releasing information, including through deposition testimony, if "[d]isclosure would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings or disclose investigative techniques and procedures the effectiveness of which would thereby be impaired." For example, your letter seeks documents describing "DEA's procedures, policies, or protocols regarding . . . analysis, utilization, and handling of" information in DEA law enforcement databases, and "DEA's efforts to assess or

track the illegal entry, distribution, or use of Prescription Opioids." Your request for depositions of DEA's former and current employees raises the same concern. The release of such information could reveal DEA's investigative techniques and enable wrongdoers to avoid detection, which is why section 16.26(b)(5) prohibits such a release.

8. Violates the Privacy Act, 5 U.S.C. § 552a

Congress enacted the Privacy Act of 1974, 5 U.S.C. § 552a, in order "to protect against invasion of an individual's personal privacy by . . . providing individuals with more control over the gathering, dissemination, and accuracy of [government] agency information about themselves." *Unger v. District Disclosure Office IRS*, 1:99-CV-698, 2000 U.S. Dist. LEXIS 16064, at *5-6 (N.D. Ohio Sep. 18, 2000). The release of personally identifiable information from a federal system of records without the individual's consent violates the Privacy Act. *Id*.

Certain items requested seek information that, if disclosed, would violate the Privacy Act and 28 C.F.R. § 16.25(b)(1), or otherwise cause an unwarranted invasion of personal privacy. For example, your request for personnel files implicates 28 C.F.R. § 16.25(b)(1). Personnel files contain sensitive personal information. The Privacy Act generally prohibits the disclosure of such information, without appropriate justification. 5 U.S.C. § 552a(b). You make no proffer why such information is necessary and germane to the litigation. Indeed, the DEA could subject itself to a private lawsuit by any individual whose data is improperly released outside its routine use. See, e.g., Kinman v. United States, No. 1:16-CV-329, 2016 U.S. Dist. LEXIS 169447, at *10 (S.D. Ohio Dec. 7, 2016) (stating that the Privacy Act "provides a private cause of action against federal agencies for violating the Act's provisions"); see also 5 U.S.C. § 552a(g)(1).

9. Available from Other Sources

Several of the documents that you request are already in the Defendants' possession, and it would be unreasonable and burdensome to seek the same documents from the DEA. For example, you seek "[a]ll Documents concerning Communications between DEA and DEA Registrants regarding any actual or purported obligation under 21 U.S.C. § 823, 21 CFR 1301.74 or any other DEA regulation with respect to suspicious orders for controlled substances, including but not limited to letters, presentations, emails, conference materials, or other correspondence." With respect to communications between DEA and Defendants regarding this matter, Defendants should already have these communications in their possession.

Availability from a more convenient source is a defense to a subpoena served on a non-party—particularly a subpoena served on a government agency that uses the data for law enforcement purposes. In *Ohio Bureau of Workers' Comp. v. MDL Active Duration Fund, Ltd.*, MDL defendants served a subpoena on the Ohio Inspector General for documents obtained through its investigation of the Bureau of Workers' Compensation. No. 2:05-CV-0673, 2006 U.S. Dist. LEXIS 82560 (S.D. Ohio 2006). The Inspector General moved to quash the subpoena, and the Court granted the motion. One of the factors the Court considered in assessing the law enforcement privilege was whether the materials were available from other sources. *Id.* at *10-11. The MDL defendants made "absolutely no showing that [they] need[ed] to obtain these documents from the Inspector General as opposed to the parties from whom the Inspector

General obtained the documents directly." *Id.* at *12. The Court described the subpoena issued by the MDL defendants as, "at best, an effort to obtain, from a single source, documents which might otherwise have to be acquired from different sources." *Id.* at *15. The Court refused to countenance such an effort, where there was a "real risk that disclosure of the documents would either jeopardize [an] investigation or subject the Inspector General, who is not a party to this litigation, to an undue burden in production." *Id.* at *16. Justifying its holding in even stronger terms, the Court said: "The only conceivable justification for this burden would be to make it more convenient for the MDL defendants to obtain documents . . . The Court [did] not believe that the burden [was] justified under these circumstances." *Id.*

* * *

The foregoing objections are not exclusive, and the DOJ and DEA reserve the right to assert further objections in response to the requests as appropriate, including privileges and protections such as the attorney-client privilege, the work product doctrine, the deliberative process privilege, the informant's privilege, and the need to withhold classified information.

After carefully considering your request, consulting with the DEA, applying all of the above factors, and reviewing the relevant procedural and substantive law, I have determined that your requests are unreasonably burdensome, cumulative, duplicative, and improper under the applicable substantive and procedural requirements. Therefore, I do not authorize the disclosure of the official information that you requested.

Sincerely,

DAVID A. SIERLEJA

First Assistant United States Attorney

Northern District of Ohio

Acting Under Authority Conferred by 28 U.S.C. § 51

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July 10, 2018

By Federal Express and Electronic Mail

James R. Bennett, Esq. Assistant United States Attorney Carl B. Stokes U.S. Courthouse 801 West Superior Avenue, Suite 400 Cleveland, Ohio 44113-1852

Re: Touhy Requests in In re National Prescription Opiate Litig., MDL No.

2804 (N.D. Ohio)

Dear Mr. Bennett:

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. In that lawsuit, we have mailed subpoenas to the following persons: (a) Kyle Wright; (b) Joseph Rannazzisi; (c) Louis Milione; (d) Demetra Ashley; (e) Charles Rosenberg; (f) Alan Santos; (g) Michael Mapes; (h) Dr. Christine Sannerud; (i) Matthew Strait; (j) Michael Leonhart; (k) Keith Martin; (l) Gregory Brodersen; (m) Denise Foster; (n) Derek Siegle; and (o) DEA. Copies of the subpoenas and accompanying correspondence are attached for your reference as Exhibits A – O.

This letter is submitted pursuant to 28 C.F.R. § 16.21 et seq, the Department of Justice *Touhy* regulations. Because these subpoenas are directed at DEA and current and former federal employees, compliance is subject to the *Touhy* process, and for that reason we have not affected formal service of process and hope that it will be unnecessary. The basis for this request is set forth below with reference to the requirements imposed by the *Touhy* regulations.

¹ Subpoenas to Keith Martin, Gregory Brodersen, and Denise Foster have not been mailed at this time, as we are unable to locate their current addresses.

I. Summary of Information Sought and its Relevance to the Proceeding

This litigation involves claims by various plaintiffs, including state attorneys general, municipalities, and counties, against DEA-registered pharmaceutical manufacturers, distributors, pharmacies and others. Plaintiffs allege, among other things, that the manufacturers and distributors violated the federal Controlled Substances Act ("CSA") and accompanying DEA regulations. The United States moved and has been granted permission to intervene in this matter as a friend of the court, and has produced national ARCOS data, which Plaintiffs relied upon to plead their claims against the defendants. The United States also has produced or will produce suspicious order reports filed with DEA by Defendants.

Plaintiffs allege that Defendants had a duty under the CSA to report and to halt shipments of suspicious orders, that Defendants breached those duties, and that Defendants' breach caused the opioid crisis. Because Plaintiffs claims are premised in whole or in part on Defendants' alleged duties under the CSA, discovery from DEA concerning DEA's communications and guidance relating to Defendants' duties under the CSA, DEA's abilities and practices relating to processing and acting upon communications from Defendants regarding suspicious activity, and DEA's assessment of the legitimate medical need for prescription opioids is crucial to Defendants' ability to defend against Plaintiffs' allegations.

As summarized below, we request documents and testimony relating to Plaintiffs' allegations that Defendants violated duties arising under the CSA. Plaintiffs' allegations span a broad timeframe throughout which various DEA personnel interacted with Defendants and developed specialized knowledge of DEA practice and procedure. Thus, Defendants believe each fact-witness possesses particularized knowledge about DEA policies, practices, and procedures throughout the timeframe at issue in this litigation.

A. Kyle J. Wright

Kyle J. Wright served as a Staff Coordinator in the Regulatory Division of the Office of Diversion Control and in the Targeting & Analysis Unit of the Office of Diversion Control. DEA previously authorized Mr. Wright to testify in the matter of *United States v. \$463,497.72 in U.S. Currency From Best Bank Account #259502677, et al.*, CV-08-11564, which was an enforcement action by DEA against a DEA-registered pharmaceutical distributor related to the distributor's compliance with the CSA. Moreover, Mr. Wright regularly communicated and coordinated with Defendants in their efforts to comply with the federal CSA. Mr. Wright also was responsible for developing and implementing what became known as the Distributor Initiative, which related to distributors of controlled substances, including Defendants in this case.

We seek documents and testimony from or concerning Mr. Wright relating but not limited to the following topics:

• DEA's interpretation, enforcement, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

- Guidance and communication provided by DEA to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74;
- DEA's interpretation, enforcement, and practices regarding the obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 or any other provision of the Controlled Substances Act and 21 C.F.R. § 1301.74 or any other implementing regulation of the Controlled Substances Act.
- DEA's practices and procedures relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS data, suspicious order reports, or other communications from DEA-registrants;
- DEA's practice of notifying DEA-registered distributors when another distributor terminated its relationship with a customer due to the risk of diversion, including DEA's decision to discontinue such practice.

B. Joseph T. Rannazzisi

Joseph Rannazzisi is a former Deputy Assistant Administrator of DEA. From 2006 to 2015, Mr. Rannazzisi was in charge of DEA's Office of Diversion Control. During his tenure, he devised and issued guidance letters to DEA registrants regarding their regulatory obligations and oversaw enforcement actions against several Defendants. Mr. Rannazzisi presided over the Office of Diversion Control at a time during which DEA practices and procedures underwent significant changes. In 2017, Mr. Rannazzisi was the lead source in a CBS "60 Minutes" and Washington Post story regarding the opioid epidemic and provided information regarding Defendants' compliance with the CSA. On information and belief, Mr. Rannazzisi has been retained as a consultant by Plaintiffs in this matter.

We seek documents and testimony from or concerning Mr. Rannazzisi relating but not limited to the following topics:

- DEA's interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Guidance and communication provided by DEA to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74;
- DEA's interpretation, enforcement, and practices regarding the obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 or any other provision of the Controlled Substances Act and 21 C.F.R. § 1301.74 or any other implementing regulation of the Controlled Substances Act;
- DEA's relationship with manufacturers and distributors during Mr. Rannazzisi's tenure in the Office of Diversion Control;

- DEA's decision not to allow Distributors access to de-identified ARCOS data prior to February 2018;
- DEA's procedures and practices relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS data, suspicious order reports, or other communications from DEA Registrants to identify and stop sources of diversion;
- DEA's procurement and manufacturing quotas for opioid medications, the basis for the quotas, and the process for establishing the quotas;
- Mr. Rannazzisi's departure from DEA, including but not limited to documents retained or removed by Mr. Rannazzisi at the time of his departure from DEA.

C. Louis J. Milione

Louis Milione is a former Assistant Administrator of DEA. From 2015 to 2017, following the departure of Mr. Rannazzisi, Mr. Milione was in charge of DEA's Office of Diversion Control. Mr. Milione regularly and personally communicated with Defendants regarding their obligations under the CSA, and testified before Congress about DEA's efforts to improve communications and relationships with DEA registrants following the departure of Mr. Rannazzisi. Moreover, during Mr. Milione's tenure, DEA announced its intent to issue a new regulation concerning suspicious orders, which would be the first amendment to or supplementation of the existing regulation since 1971.

We seek documents and testimony from or concerning Mr. Milione relating but not limited to the following topics:

- DEA's interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Guidance and communication provided by DEA to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74;
- DEA's interpretation, enforcement, and practices regarding the obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 or any other provision of the Controlled Substances Act and 21 C.F.R. § 1301.74 or any other implementing regulation of the Controlled Substances Act;
- DEA's need for and intent to issue new regulations concerning suspicious orders;
- DEA's relationship with manufacturers and distributors during Mr. Milione's tenure in the Office of Diversion Control;
- DEA's procedures and practices relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS data, suspicious order reports, or other communications from DEA Registrants to identify and stop sources of diversion;

• DEA's communications relating to and efforts to comply with the reports and recommendations of the Government Accountability Office concerning DEA's administration of the quota process for controlled substances² and DEA's need for improved communication with DEA Registrants.³

D. Demetra Ashley

Demetra Ashley is a former Acting Assistant Administrator of DEA and a former Diversion Program Manager in Chicago. During her tenure as Acting Assistant Administrator, Ms. Ashley served in the Office of Diversion Control under Mr. Milione. Ms. Ashley regularly and personally communicated with Defendants at industry conferences and through email regarding their regulatory obligations.

We seek documents and testimony from or concerning Ms. Ashley relating but not limited to the following topics:

- DEA's interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Guidance and communication provided by DEA to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74;
- DEA's interpretation, enforcement, and practices regarding the obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 or any other provision of the Controlled Substances Act and 21 C.F.R. § 1301.74 or any other implementing regulation of the Controlled Substances Act;
- DEA's relationship with manufacturers and distributors during Ms. Ashley's tenure in the Office of Diversion Control;

E. Charles P. Rosenberg

Charles Rosenberg is a former Acting Administrator of DEA. He was appointed in May 2015 following the resignation of Administrator Michele Leonhart. Mr. Rosenberg spoke at industry conferences concerning DEA's relationship with its registrants, and testified before Congress of the need for better cooperation with registrants. Mr. Rosenberg also testified concerning DEA's willingness to provide guidance and direction to registrants in fulfilling their regulatory obligations.

We seek documents and testimony from or concerning Mr. Rosenberg relating but not limited to the following topics:

² See Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed: Coordination between DEA and FDA Should Be Improved, GAO-15-202 (Washington, D.C.: February 2, 2015)

³ See Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access, GAO-15-471 (Washington, D.C.: June 25, 2015)

- DEA's interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Guidance and communication provided by DEA to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74;
- DEA's interpretation, enforcement, and practices regarding the obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 or any other provision of the Controlled Substances Act and 21 C.F.R. § 1301.74 or any other implementing regulation of the Controlled Substances Act;
- DEA's relationship with manufacturers and distributors during Mr. Rosenberg's tenure as Acting Administrator;
- Mr. Rosenberg's testimony before various committees of the United States Senate and United States House of Representatives.

F. Alan G. Santos

Alan Santos is a former Associate Deputy Administrator of DEA in the office of Diversion Control. From 2011 to 2014, Mr. Santos worked under Mr. Rannazzisi and personally communicated with DEA registrants regarding their suspicious order monitoring systems.

We seek documents and testimony from or concerning Mr. Santos relating but not limited to the following topics:

- DEA's interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Guidance and communication provided by DEA to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74;
- DEA's interpretation, enforcement, and practices regarding the obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 or any other provision of the Controlled Substances Act and 21 C.F.R. § 1301.74 or any other implementing regulation of the Controlled Substances Act;
- DEA's relationship with manufacturers and distributors during his tenure in the Office of Diversion Control;
- DEA's procedures and practices relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS data, suspicious order reports, or other communications from DEA Registrants to identify and stop sources of diversion;

• DEA's procurement and manufacturing quotas for opioid medications, the basis for the quotas, and the process for establishing the quotas;

G. Michael Mapes

Michael Mapes was head of the eCommerce Section of the Office of Diversion Control. Throughout the relevant timeframe, Mr. Mapes handled and analyzed ARCOS and CSOS data provided by DEA registrants. Mr. Mapes regularly and personally communicated with Defendants regarding their duties under the CSA and has direct knowledge of DEA's capabilities with respect to the processing and analyzing of ARCOS data.

We seek documents and testimony from or concerning Mr. Mapes relating but not limited to the following topics:

- DEA's interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Guidance and communication provided by DEA to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74;
- DEA's interpretation, enforcement, and practices regarding the obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 or any other provision of the Controlled Substances Act and 21 C.F.R. § 1301.74 or any other implementing regulation of the Controlled Substances Act;
- DEA registrants' obligation to submit ARCOS and CSOS data, including the nature of the information and how registrants submitted the data to DEA historically;
- DEA's practices, procedures, and capabilities for processing and analyzing ARCOS and CSOS data to target diversion;

H. Dr. Christine Sannerud

Dr. Christine Sannerud is a Section Chief in the United Nations Reporting & Quota Section of the Office of Diversion Control. Dr. Sannerud's unit oversees the establishment and processing of procurement and manufacturing quotas, which reflect DEA's judgment concerning the legitimate medical, scientific, and industrial need for individual controlled substances. Because Plaintiffs in this lawsuit allege that Defendants manufactured and distributed prescription opioids in excess of legitimate medical need, Dr. Sannerud possesses particularized knowledge concerning the allegations in this lawsuit.

We seek documents and testimony from or concerning Dr. Sannerud relating but not limited to the following topics:

• DEA's practices and procedures relating to the establishment of procurement and manufacturing quotas for prescription opioids;

- The basis for procurement and manufacturing quotas of prescription opioids from 1995 to 2018.
- DEA's procedures, process, approach, and criteria used to determine the legitimate medical, scientific, and industrial needs for prescription opioids and setting production quotas based upon those determinations.

I. Matthew Strait

Matthew Strait is a Senior Policy Advisor at DEA with experience in the United Nations Reporting & Quota Section of the Office of Diversion Control. Mr. Strait was involved in the establishment and processing of procurement and manufacturing quotas, which reflect DEA's judgment concerning the legitimate medical, scientific, and industrial need for individual controlled substances.

We seek documents and testimony from or concerning Mr. Strait relating but not limited to the following topics:

- DEA's practices and procedures relating to the establishment of procurement and manufacturing quotas for prescription opioids;
- The basis for procurement and manufacturing quotas of prescription opioids from 1995 to 2018.
- DEA's procedures, process, approach, and criteria used to determine the legitimate medical, scientific, and industrial needs for prescription opioids and setting production quotas based upon those determinations

J. Michele Leonhart

Michele Leonhart is the former Acting Administrator and Administrator of DEA. Ms. Leonhart served as Acting Administrator from 2007 to 2010 and as Administrator from 2010 to 2015. During her tenure, and in her capacity as Administrator, Ms. Leonhart authorized and signed DEA procurement and manufacturing quotas for prescription opioids.

We seek documents and testimony from or concerning Ms. Leonhart relating but not limited to the following topics:

- DEA's interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Guidance and communication provided by DEA to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74;
- DEA's interpretation, enforcement, and practices regarding the obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823

- or any other provision of the Controlled Substances Act and 21 C.F.R. § 1301.74 or any other implementing regulation of the Controlled Substances Act;
- DEA's practices and procedures relating to the establishment of procurement and manufacturing quotas for prescription opioids;
- The basis for procurement and manufacturing quotas of prescription opioids from 1995 to 2018.
- DEA's procedures, process, approach, and criteria used to determine the legitimate medical, scientific, and industrial needs for prescription opioids and setting production quotas based upon those determinations

K. Keith Martin

Keith Martin has served as the Assistant Special Agent in Charge of the Drug Enforcement Administration's Office in Cleveland from 2015 through the present. Mr. Martin is also a member of the United States Attorney for the North District of Ohio's Heroin and Opioid Task Force. Mr. Martin is involved in opioid-specific enforcement and oversees enforcement teams targeting high level traffickers of heroin and fentanyl, including the Mexican Cartel throughout the areas relevant to this lawsuit. Mr. Martin also meets with representatives of Plaintiff Summit County regarding opioid-specific enforcement in Summit County.

We seek documents and testimony from or concerning Mr. Martin relating but not limited to the following topics:

- DEA's communications with any representative of Summit County, OH; Akron, OH; Cleveland, OH; and/or Cuyahoga County, OH regarding or relating to prescription opioids;
- DEA's efforts relating to the Summit County, OH Drug Unit along with any communications with any members of the Summit County, OH Drug Unit;
- DEA's efforts relating to the United States Attorney for the North District of Ohio's Heroin and Opioid Task Force;
- Any and all efforts to combat diversion, respond to the Opioid epidemic, or form a
 joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH;
 Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within
 Summit County or Cuyahoga County;
- DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances.

L. Gregory Brodersen

Gregory Brodersen has served as a Drug Enforcement Administration Agent for an area including Summit County, OH. Mr. Brodersen was involved in the Summit County Drug Unit from at least 2011 to 2016 and attended Summit County Drug Unit meetings.

We seek documents and testimony from or concerning Mr. Brodersen relating but not limited to the following topics:

- DEA's communications with any representative of Summit County, OH; Akron, OH; Cleveland, OH; and/or Cuyahoga County, OH regarding or relating to prescription opioids;
- DEA's efforts relating to the Summit County, OH Drug Unit along with any communications with any members of the Summit County, OH Drug Unit;
- Any and all efforts to combat diversion, respond to the Opioid epidemic, or form a
 joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH;
 Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within
 Summit County or Cuyahoga County;
- DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances.

M. Denise Foster

Denise Foster served as the Group Supervisor of the DEA Cleveland Resident Office Tactical Diversion Squad, a task force assigned to deal with prescription drug abuse from at least 2012 through 2014. Ms. Foster was involved in investigating pharmacies engaged in the alleged diversion of prescription medication.

We seek documents and testimony from or concerning Ms. Foster relating but not limited to the following topics:

- DEA's communications with any representative of Summit County, OH; Akron, OH; Cleveland, OH; and/or Cuyahoga County, OH regarding or relating to prescription opioids;
- DEA's efforts relating to the Summit County, OH Drug Unit along with any communications with any members of the Summit County, OH Drug Unit;
- Any and all efforts to combat diversion, respond to the Opioid epidemic, or form a
 joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH;
 Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within
 Summit County or Cuyahoga County;

- The practices and policies of the DEA Cleveland Resident Office Tactical Diversion Squad, including any investigations or inquiries relating to the abuse, misuse, or and/or diversion of prescription opioids;
- DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other
 prescribers in the City of Cleveland, the City of Akron, Cuyahoga County, or
 Summit County, or any township, village, or city within Summit County or
 Cuyahoga County, prior to registering them or renewing their registration to
 lawfully prescribe or dispense controlled substances.

N. Derek Siegle

Derek Siegle serves as Executive Director of the Ohio High Intensity Drug Trafficking ("HIDTA") Program and has held this position since August 2009. In April of 2018, Mr. Siegle testified before Congress about the role that the Ohio High Intensity Drug Trafficking Program has in combatting the opioid crisis._DEA plays an active role in the administration of the High Intensity Drug Trafficking Area Program that Mr. Siegle leads.

We seek documents and testimony from or concerning Mr. Siegle relating but not limited to the following topics:

- DEA policies and procedures relating to the HIDTA program;
- Any and all efforts by DEA relating to the HIDTA program in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County;
- Ohio HIDTA's communications with any representative of Summit County, OH; Cleveland, OH; and/or Cuyahoga County, OH regarding or relating to prescription opioids;
- Ohio HIDTA's efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County;
- Ohio HIDTA's efforts to investigate any pharmacists, pharmacy interns, doctors or
 other prescribers in the City of Cleveland, the City of Akron, Cuyahoga County, or
 Summit County, or any township, village, or city within Summit County or
 Cuyahoga County, prior to registering them or renewing their registration to
 lawfully prescribe or dispense controlled substances.

O. 30(b)(6) Testimony

In addition to testimony from the fact witnesses listed above, each of whom have particularized and personal knowledge of allegations in this lawsuit, Defendants request documents and testimony pursuant to Fed. R. Civ. P. 30(b)(6) from DEA. As set forth in the attached subpoena (Ex. O), we seek testimony concerning the following topics:

- The organizational structure of the Office of Diversion Control and the Detroit Diversion Office, the Cleveland, OH Resident Office, the Youngstown, OH Resident Office, the Cleveland Tactical Diversion Squad, and any other unit or subunit of DEA with responsibilities in the state of Ohio;
- DEA's interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Guidance or other communications provided by DEA to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74;
- DEA's involvement in lawsuits brought against DEA-registered distributors by customers whose orders of controlled substances had been blocked based on the distributor's determination that the orders were "suspicious" pursuant to 21 C.F.R. § 1301.74, or whose ability to purchase controlled substances had been denied or terminated;
- DEA's interpretation, enforcement, and practices regarding any obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- The use or potential use of Prescriber Data in connection with any obligation under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- DEA's efforts to assess or track the illegal entry, distribution, or use of opioids, including heroin, illegal fentanyl or carfentanyl, counterfeit opioid pills, or stolen Prescription Opioids in the state of Ohio;
- Inquiries or complaints received by DEA from any government officials of the Ohio Board of Pharmacy, the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County regarding suspicious order reports pursuant to 21 C.F.R. § 1301.74, or suspected or actual diversion of Prescription Opioids;
- DEA's procedures and practices relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS Data, suspicious order reports, or other communications from DEA Registrants to identify and stop sources of diversion;
- Investigations or inquiries by DEA concerning the Defendants;
- DEA's practice of notifying DEA-registered distributors when another distributor terminated its relationship with a customer due to the risk of diversion, including DEA's decision to discontinue such practice;
- DEA's decision not to allow DEA-registered distributors access to de-identified ARCOS Data prior to February 2018, and its decision to provide DEA-registered distributors with limited access to certain ARCOS Data in February 2018;

- DEA's practices and procedures relating to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids;
- The basis for Opioid Procurement Quotas and Opioid Production Quotas of Prescription Opioids from 1995 to 2018;
- DEA's procedures, process, approach, and criteria used to determine the legitimate medical, scientific, and industrial needs for prescription opioids and setting production quotas based upon those determinations;
- Communications between DEA and any of the Defendants;
- Communications between DEA and the Board of Pharmacy of any State, the Attorney General of any State, or government officials of the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County relating to Prescription Opioids or Illicit Opioids;
- DEA's policies, procedures, practices, and experience regarding the sharing of ARCOS Data with state and local law enforcement entities when requested by them in connection with investigations of or suspicions regarding possible diversion by DEA-registrants in their jurisdictions;
- DEA policies and procedures relating to the HIDTA Program;
- The HIDTA Program's efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County;
- DEA's communications relating to and efforts to comply with the reports and recommendations of the Government Accountability Office;
- DEA's expenditure of funds allocated to the Diversion Control Fee Account;
- DEA's process for licensing prescribers of controlled substances;
- Investigation into the retention or removal of documents by Joseph Rannazzisi, and any other former DEA employees currently retained by Plaintiffs.

Defendants' requests for production of documents are also attached as Exhibit O.

II. Disclosure is Warranted Under 28 C.F.R. § 16.26

Pursuant to DOJ's *Touhy* regulations, the Deputy or Associate Attorney General assesses the following considerations in determining whether disclosure is warranted:

- (a)(1) Whether such disclosure is appropriate under the rules of procedure governing the case or matter in which the demand arose;
- (a)(2) Whether disclosure is appropriate under the relevant substantive law of privilege.

This request satisfies both of these considerations. As explained previously, the requested documents and testimony directly concern the allegations in this lawsuit. Plaintiffs allege Distributors violated regulatory duties arising under the CSA, and the requested information is relevant to determining the nature of the alleged regulatory duties, the reasonableness of Defendants' conduct, and the role of Defendants in causing the injuries alleged by Plaintiffs. Moreover, Defendants do not request privileged documents.

Additionally, DOJ's *Touhy* regulations prohibit disclosure, subject to certain exceptions, if any of the following factors exist:

- (b)(1) Disclosure would violate a statute, such as the income tax laws, 26 U.S.C. 6103 and 7213, or a rule of procedure, such as the grand jury secrecy rule, F.R.Cr.P., Rule 6(e),
- (b)(2) Disclosure would violate a specific regulation;
- (b)(3) Disclosure would reveal classified information, unless appropriately declassified by the originating agency,
- (b)(4) Disclosure would reveal a confidential source or informant, unless the investigative agency and the source or informant have no objection,
- (b)(5) Disclosure would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings or disclose investigative techniques and procedures the effectiveness of which would thereby be impaired,
- (b)(6) Disclosure would improperly reveal trade secrets without the owner's consent.

This request is not intended to implicate any of these considerations. To the extent DOJ or DEA believe any of the requested information does implicate these considerations, Defendants are willing to work with DOJ, if possible, to narrow the scope of the request. The requested information is within the scope of ordinary subpoena practice and does not seek disclosure of information prohibited by statute or regulation, nor information that is classified or that would reveal the source of an informant. To the extent Defendants request investigatory records compiled for law enforcement purposes, Defendants do not request investigatory records that would interfere with ongoing enforcement proceedings. Further, in abundance of caution and to avoid any concern that disclosure of investigatory records would reveal "investigative techniques and procedures the effectiveness of which would thereby be impaired," Defendants request that the information be provided as highly confidential pursuant to the protective order governing this matter (attached as Ex. P).

III. Expedited Response

As you are aware, the deadline for fact discovery in this matter is August 31, 2018. Accordingly, we ask that you work with Defendants to establish a reasonable schedule for disclosure of the requested documents and completion of testimony prior to that date.

Please contact me directly at (202) 434-5000 or emainigi@wc.com if you have questions concerning these subpoenas or require additional information.

Sincerely,

/s/ Enu Mainigi
Enu Mainigi

Counsel for Defendant Cardinal Health, Inc. Co-Liaison Counsel for the Distributor Defendants

/s/ Mark S. Cheffo
Mark Steven Cheffo

Counsel for Defendants Purdue Pharma L.P., Purdue Pharma Inc., and the Purdue Frederick Company.

Co-Liaison Counsel for the Manufacturer Defendants

/s/ Carole S. Rendon
Carole Schwartz Rendon

Counsel for Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.

Co-Liaison Counsel for the Manufacturer Defendants

/s/ Shannon E. McClure
Shannon E. McClure

Counsel for Defendant AmerisourceBergen Drug Corporation.

Co-Liaison Counsel for the Distributor Defendants

/s/ Geoffrey Hobart
Geoffrey Hobart

Counsel for Defendant McKesson Corporation

Co-Liaison Counsel for the Distributor Defendants

s/ Kaspar Stoffelmayr
Kaspar Stoffelmayr

Counsel for the Walgreens Defendants.

Co-Liaison Counsel for the Chain Pharmacy Defendants Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 23 of 154. PageID #: 18748

EXHIBIT A

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.

ENU MAINIGI (202) 434-5420 emainigi@wc.com WASHINGTON, D. C. 20005-5901 (202) 434-5000 FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Mr. Kyle J. Wright 22 Sassafras Ln Stafford, VA 22554-7871

Re: Subpoena in In re National Prescription Opiate Litig., MDL No. 2804

(N.D. Ohio)

Dear Mr. Wright:

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning this subpoena or require additional information.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi

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J.Fa.

UNITED STATES DISTRICT COURT

for the

		ct of Ohio
P	cription Opiate Litigation Jaintiff	Civil Action No. 1:17-md-02804-DAP (If the action is pending in another district, state where:
SU	BPOENA TO TESTIFY AT A DE	CPOSITION IN A CIVIL ACTION
	Sassafras Ln, Stafford, VA 22554-78	
eposition to be taken in ne or more officers, dire	this civil action. If you are an organ	t the time, date, and place set forth below to testify at a ization that is <i>not</i> a party in this case, you must designate ate other persons who consent to testify on your behalf at:
Place: 725 Twelfth St. N	IW, Washington, D.C. 20005	Date and Time:
Place: 725 Twelfth St. N	IW, Washington, D.C. 20005	Date and Time: 9:00AM, 08/10/2018
The deposition w	rill be recorded by this method: Ste	
The deposition was a second of the deposition was a second of the deposition. You electronically stomaterial:	rill be recorded by this method: Standard, or your representatives, must also red information, or objects, and perrof Fed. R. Civ. P. 45(c), relating to your	9:00AM, 08/10/2018 enographic and/or by video and audio recording bring with you to the deposition the following documents nit their inspection, copying, testing, or sampling of the our protection as a person subject to a subpoena, and Rule na and the potential consequences of not doing so, are
The deposition we related to the deposition we related to the relating to the	ill be recorded by this method: Step of Fed. R. Civ. P. 45(c), relating to your duty to respond to this subpoets.	9:00AM, 08/10/2018 enographic and/or by video and audio recording bring with you to the deposition the following documents nit their inspection, copying, testing, or sampling of the our protection as a person subject to a subpoena, and Rule na and the potential consequences of not doing so, are OURT OR /s/ Enu Mainigi
The deposition we relect the provisions of tached. The provisions of tached.	rill be recorded by this method: Step 1, or your representatives, must also red information, or objects, and perrof Fed. R. Civ. P. 45(c), relating to your duty to respond to this subpose	9:00AM, 08/10/2018 enographic and/or by video and audio recording bring with you to the deposition the following documents nit their inspection, copying, testing, or sampling of the our protection as a person subject to a subpoena, and Rule na and the potential consequences of not doing so, are OURT OR /s/ Enu Mainigi Attorney's signature

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

-	r (name of individual and title, if any)		
s received by me on (do	ite)		
☐ I served the su	bpoena by delivering a copy to the nar	med individual as follows:	
		on (date) ; or	
☐ I returned the	subpoena unexecuted because:		
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I declare under pe	enalty of perjury that this information i	s true.	
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		server s signature	
		Printed name and title	
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Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- **(B)** Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- **(A)** When Required. On timely motion, the issuing court must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- **(B)** When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information;
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or
- (iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

- (1) Producing Documents or Electronically Stored Information.

 These procedures apply to producing documents or electronically stored information:
- **(A)** *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- **(B)** Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
- (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.
- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

- **(A)** *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 28 of 154. PageID #: 18753

EXHIBIT B

LAW OFFICES

WILLIAMS & CONNOLLY LLP

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23

WASHINGTON, D. C. 20005-5901 (202) 434-5000 FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988) PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Mr. Joseph Rannazzisi 7812 Ashley Glen Rd Annandale, VA 22003-1555

> Subpoenas in In re National Prescription Opiate Litig., MDL No. 2804 Re: (N.D. Ohio)

Dear Mr. Rannazzisi:

I write on behalf of Defendants in the matter of In re National Prescription Opiate Litigation, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find copies of (1) a federal subpoena for witness testimony calling for your appearance at a deposition, and (2) a federal subpoena for the production of documents. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ Touhy regulations and the involvement of the United States Attorney for the Northern District of Ohio, see 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning these subpoenas or require additional information.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi

· ... 25s.

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

	Northern District of	Onio	
To: Joseph T. Rannazzisi, 7812	A TO TESTIFY AT A DEPO Ashley Glen Rd, Annandale, Vo Commander of the action. If you are an organization anaging agents, or designate of the second companies of the action.	A 22003-1555 time, date, and place se on that is <i>not</i> a party in	ACTION et forth below to testify at a this case, you must designate
Place: 725 Twelfth St. NW, Wash	ington, D.C. 20005	Date and Time: 08/13/	/2018, 9:00AM
☐ Production: You, or your	representatives, must also brin nation, or objects, and permit t	g with you to the deposi	ition the following documents,
45 (d) and (e), relating to your duty attached. Date:07/10/2018	Civ. P. 45(c), relating to your py to respond to this subpoena a	nd the potential consequ	bject to a subpoena, and Rule nences of not doing so, are
Siz	gnature of Clerk or Deputy Clerk		/s/ Enu Mainigi Attorney's signature
The name, address, e-mail, and tele All Defendants Enu Mainigi, 725 Twelfth St. NW, W		, who issues or	requests this subpoena, are:

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena fo as received by me on (da			
☐ I served the su	abpoena by delivering a copy to the nar	ned individual as follows:	
		on (date) ; or	***************************************
☐ I returned the	subpoena unexecuted because:		
Unless the subpo	ena was issued on behalf of the United itness fees for one day's attendance, ar	States, or one of its officers or agents, land the mileage allowed by law, in the an	I have also nount of
_	•		
y fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under p	enalty of perjury that this information i	s true.	
te:			
		Server's signature	
		Printed name and title	
	and the second s	Server's address	

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

112.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- **(A)** When Required. On timely motion, the issuing court must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- **(B)** When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information;
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or
- (iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

- (1) *Producing Documents or Electronically Stored Information*. These procedures apply to producing documents or electronically stored information:
- (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- **(B)** Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
- (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.
- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

25.34

United States District Court

for the

Northern District of Ohio

	Nothern District	or Onio
In re National Pre	escription Opiate Litigation	
	Plaintiff) v.)	Civil Action No. 1:17-md-02804-DAP
	Defendant)	
	POENA TO PRODUCE DOCUMENT OR TO PERMIT INSPECTION OF PR	
To:	Joseph T. Rannazzisi, 7812 Ashley G	en Rd, Annandale, VA 22003-1555
***************************************	(Name of person to whom	his subpoena is directed)
documents, electronica material: See Schedule	ally stored information, or objects, and to	the time, date, and place set forth below the following permit inspection, copying, testing, or sampling of the
Place:		Date and Time:
		07/31/2018 9:30 am
other property possess	ed or controlled by you at the time, date,	permit entry onto the designated premises, land, or and location set forth below, so that the requesting party operty or any designated object or operation on it. Date and Time:
Rule 45(d), relating to	provisions of Fed. R. Civ. P. 45 are attac your protection as a person subject to a s na and the potential consequences of not	ned – Rule 45(c), relating to the place of compliance; abpoena; and Rule 45(e) and (g), relating to your duty to doing so.
	CLERK OF COURT	
	C.22.11. C. T.	OR /s/ Enu Mainigi
	Signature of Clerk or Deputy Clerk	Attorney's signature
	nail address, and telephone number of the	
All Defendants		, who issues or requests this subpoena, are:
Enu Mainigi, 725 Twel	fth St. NW, Washington, DC 20005, emai	nigi@wc.com, 202-434-5000

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

(date)	·		
☐ I served the su	bpoena by delivering a copy to the nar	ned person as follows:	
		on (date)	; or
	subpoena unexecuted because:		
Unless the subpostendered to the wi	ena was issued on behalf of the United tness the fees for one day's attendance	States, or one of its officers or agents, le, and the mileage allowed by law, in the	have also e amount of
\$	•		
/ fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under pe	enalty of perjury that this information i	s true.	
e:		Server's signature	
		Printed name and title	
		Server's address	

Additional information regarding attempted service, etc.:

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action(Page 3)

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

- (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
- (ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
 - (B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(e);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information; or

- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
 - (ii) ensures that the subpoenaed person will be reasonably compensated.

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(e) Duties in Responding to a Subpoena.

- (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
- (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- **(B)** Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
- (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.
- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

DEFINITIONS

The following terms shall have the meanings set forth below. Other terms shall have their plain meaning.

- 1. "Communication" means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
- 2. "Document" has the full meaning ascribed to it by Federal Rule of Civil Procedure 34(a), and means the complete original (or complete copy where the original is unavailable) and each non-identical copy (where different from the original because of notes made on the copy or otherwise) of any writing or record, including, but not limited to, all written, typewritten, handwritten, printed, or graphic matter of any kind or nature, however produced or reproduced, any form of collected data for use with electronic data processing equipment, and any mechanical or electronic visual or sound recordings or text messages in your possession, custody, or control. "Documents" include, but are not limited to, books, papers, contracts, memoranda, invoices, correspondence, notes, studies, reports, manuals, photographs, drawings, charts, graphs, data compilations, other writings, microfilm, microfiche, audio recordings, video recordings, electronic mail, and any other information stored in electronic form, and each different version or copy of each Document, including, but not limited to, drafts.
- 3. "Opioids" means substances that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, and illicit substances such as heroin, fentanyl, carfentanil, other fentanyl-type analogs, and counterfeit opioid medications.

DOCUMENTS TO BE PRODUCED

1. All documents, including communications, obtained in the course of your employment at DEA relating to Opioids.

Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 37 of 154. PageID #: 18762

EXHIBIT C

120

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.

ENU MAINIGI (202) 434-5420 emainigi@wc.com WASHINGTON, D. C. 20005-5901 (202) 434-5000 FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988) PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Mr. Louis Milione 5418 Lick River Ln Gainesville, VA 20155-1385

> Subpoena in In re National Prescription Opiate Litig., MDL No. 2804 Re:

(N.D. Ohio)

Dear Mr. Milione:

I write on behalf of Defendants in the matter of In re National Prescription Opiate Litigation, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ Touhy regulations and the involvement of the United States Attorney for the Northern District of Ohio, see 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning this subpoena or require additional information.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi

UNITED STATES DISTRICT COURT

for the

	Northern	District of	Ohio
Pl De,	cription Opiate Litigation claintiff V. fendant RPOENA TO TESTIFY AT)))	Civil Action No. 1:17-md-02804-DAP (If the action is pending in another district, state where:) SITION IN A CIVIL ACTION
To: Louis Milione, 5418	Lick River Ln, Gainesville, VA	. 20155-138	85
deposition to be taken in to one or more officers, dire about the following matter	this civil action. If you are an ctors, or managing agents, or cers, or those set forth in an attached	organizatio designate of	time, date, and place set forth below to testify at a on that is <i>not</i> a party in this case, you must designate ther persons who consent to testify on your behalf
Place: 725 Twelfth St. N	IW, Washington, D.C. 20005		Date and Time: 08/7/2018, 9:00AM
material:			eir inspection, copying, testing, or sampling of the
The provisions of 45 (d) and (e), relating to attached.	f Fed. R. Civ. P. 45(c), relating your duty to respond to this su	to your pr ubpoena an	rotection as a person subject to a subpoena, and Rule and the potential consequences of not doing so, are
Date: 07/10/2018	SANDY OPACICH, CLERK	OF COURT	<i>T</i> OR /s/ Enu Mainigi
	Signature of Clerk or Deput	ty Clerk	Attorney's signature
All Defendants	il, and telephone number of the		, who issues or requests this subpoena, are:
All Defendants	il, and telephone number of the	e attorney r	representing (name of party), who issues or requests this subpoens

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

ns received by me on (da	·		
☐ I served the sul	ppoena by delivering a copy to the nam	ed individual as follows:	
		on (date) ; or	and the second of the second o
☐ I returned the s	subpoena unexecuted because:		
Unless the subpoetendered to the wi	ena was issued on behalf of the United tness fees for one day's attendance, an	States, or one of its officers or agents, I d the mileage allowed by law, in the am	have also ount of
\$	•		
fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under pe	nalty of perjury that this information is	s true.	
e:			
		Server's signature	
		Printed name and title	
		Server's address	

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

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- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
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- (i) disclosing a trade secret or other confidential research, development, or commercial information;
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or
- (iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

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- (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
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(2) Claiming Privilege or Protection.

- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
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- (e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 42 of 154. PageID #: 18767

EXHIBIT D

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Ms. Demetra Ashley 220 20th St S Apt 813 Arlington, VA 22202-3626

Re: Subpoena in *In re National Prescription Opiate Litig.*, MDL No. 2804 (N.D. Ohio)

Dear Ms. Ashley:

150

ENU MAINIGI

(202) 434-5420

emainigi@wc.com

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning this subpoena or require additional information.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi

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· . 25.

UNITED STATES DISTRICT COURT

for the

Northern Distri	ct of Ohio
In re: National Prescription Opiate Litigation	
Plaintiff)	
v.)	Civil Action No. 1:17-md-02804-DAP
)	(If the action is pending in another district, state where:
Defendant))
SUBPOENA TO TESTIFY AT A DE	EPOSITION IN A CIVIL ACTION
To: Demetra Ashley, 220 20th St S Apt 813, Arlington, VA 2	
Testimony: YOU ARE COMMANDED to appear a deposition to be taken in this civil action. If you are an organ one or more officers, directors, or managing agents, or design about the following matters, or those set forth in an attachment	nization that is <i>not</i> a party in this case, you must designate nate other persons who consent to testify on your behalf
Place: 725 Twelfth St. NW, Washington, D.C. 20005	Date and Time:
Place: 725 Twellin St. NVV, Washington, B.C. 20005	9:00AM, 08/14/2018
All streets	3.007 NVI, 007 14720 70
	bring with you to the deposition the following documents, nit their inspection, copying, testing, or sampling of the
The provisions of Fed. R. Civ. P. 45(c), relating to you 45 (d) and (e), relating to your duty to respond to this subpoe attached. Date:	
	/s/ Enu Mainigi
Signature of Clerk or Deputy Clerk	
Th	may representing (
The name, address, e-mail, and telephone number of the attor	
All Defendants	, who issues or requests this subpoena, are:
Enu Mainigi, 725 Twelfth St. NW, Washington, DC 20005, ema	ainigi@wc.com, 202-434-5000

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

-	r (name of individual and title, if any) ate)		
☐ I served the su	abpoena by delivering a copy to the nar	med individual as follows:	
		on (date) ; or	411 1844 August 18
☐ I returned the	subpoena unexecuted because:		
		States, or one of its officers or agents, Ind the mileage allowed by law, in the an	
\$	•		
y fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under pe	enalty of perjury that this information i	s true.	
te:		Server's signature	
		Printed name and title	
		Server's address	

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- **(A)** When Required. On timely motion, the issuing court must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- **(B)** When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information;
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or
- (iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
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(d) Duties in Responding to a Subpoena.

- (1) Producing Documents or Electronically Stored Information.

 These procedures apply to producing documents or electronically stored information:
- (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- **(B)** Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
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- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 47 of 154. PageID #: 18772

EXHIBIT E

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Mr. Charles P. Rosenberg 3523 N Nottingham St Arlington, VA 22207-1335

ENU MAINIGI

(202) 434-5420

emainigi@wc.com

Re: Subpoena in *In re National Prescription Opiate Litig.*, MDL No. 2804 (N.D. Ohio)

Dear Mr. Rosenberg:

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning this subpoena or require additional information.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

		istrict of Onio	
To: Charles P. Rosenberg, 352	NA TO TESTIFY AT A) (If the action) A DEPOSITION Ington, VA 22207-13	
deposition to be taken in this civ	il action. If you are an or or managing agents, or de- hose set forth in an attach	rganization that is signate other perso	not a party in this case, you must designate ons who consent to testify on your behalf
☐ Production: You, or yo	ur representatives, must a	also bring with you	d/or by video and audio recording u to the deposition the following documents, ction, copying, testing, or sampling of the
45 (d) and (e), relating to your d attached. Date: 07/10/2018	R. Civ. P. 45(c), relating to the subset of	ppoena and the pot	as a person subject to a subpoena, and Rule rential consequences of not doing so, are
	Signature of Clerk or Deputy	Clerk	Attorney's signature
The name, address, e-mail, and t	telephone number of the a	attorney representi	ing (name of party)

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

s received by me on (da	te)		
☐ I served the sul	opoena by delivering a copy to the nar	ned individual as follows:	
- 10 - 10 - 10 - 10 - 10 - 10 - 10 - 10		on (date) ; or	
Unless the subpoetendered to the wi	ena was issued on behalf of the United tness fees for one day's attendance, ar	States, or one of its officers or agents, and the mileage allowed by law, in the a	I have also mount of
\$	•		
fees are \$	for travel and \$	for services, for a total of \$	0.00
I daglara undar na	nalty of perjury that this information i	s true	
r decrare under pe	marty of perjury that this information?	s irue.	
e:		Server's signature	
		server's signature	
		Printed name and title	A A
		Server's address	

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

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EXHIBIT F

Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 53 of 154. PageID #: 18778

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W. WASHINGTON, D. C. 20005-5901 (202) 434-5000

FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Mr. Alan Santos 6075 Erinblair Loop Haymarket, VA 20169-2613

Re: Subpoena in *In re National Prescription Opiate Litig.*, MDL No. 2804 (N.D. Ohio)

Dear Mr. Santos:

ENU MAINIGI

(202) 434-5420

emainigi@wc.com

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

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Sincerely,

/s/ Enu Mainigi
Enu Mainigi

UNITED STATES DISTRICT COURT

for the

Northern D	istrict of Ohio
In re: National Prescription Opiate Litigation Plaintiff v. Defendant) Civil Action No. 1:17-md-02804-DAP (If the action is pending in another district, state where:)
SUBPOENA TO TESTIFY AT A	DEPOSITION IN A CIVIL ACTION
To: Alan Santos, 6075 Erinblair Loop, Haymarket, VA 20	0169-2613
deposition to be taken in this civil action. If you are an or	ar at the time, date, and place set forth below to testify at a reganization that is <i>not</i> a party in this case, you must designate signate other persons who consent to testify on your behalf ment:
Place: 725 Twelfth St. NW, Washington, D.C. 20005	Date and Time:
	08/15/2018, 9:00AM
	lso bring with you to the deposition the following documents, permit their inspection, copying, testing, or sampling of the
The provisions of Fed. R. Civ. P. 45(c), relating to 45 (d) and (e), relating to your duty to respond to this subpattached.	o your protection as a person subject to a subpoena, and Rule poena and the potential consequences of not doing so, are
Date: 07/10/2018 SANDY OPACICH, CLERK OF	F <i>COURT</i> OR /s/ Enu Mainigi
Signature of Clerk or Deputy C	
The name, address, e-mail, and telephone number of the an All Defendants Enu Mainigi, 725 Twelfth St. NW, Washington, DC 20005, e	, who issues or requests this subpoena, are:

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

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This subpoena for	(name of individual and title, if any)		
was received by me on (da	nte)		
☐ I served the su	bpoena by delivering a copy to the n	amed individual as follows:	
		on (date) ; or	
☐ I returned the s	subpoena unexecuted because:		***************************************
		ed States, or one of its officers or agents, I and the mileage allowed by law, in the an	
\$	·		
My fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under pe	enalty of perjury that this information	n is true.	
Oate:			
/atc.		Server's signature	
. *		Printed name and title	
		Printea name ana title	
			il erita de la companya de la compa
		Server's address	

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EXHIBIT G

LAW OFFICES

WILLIAMS & CONNOLLY LLP

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WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Mr. Michael Mapes 3510 Hollycrest Dr Colorado Springs, CO 80920-3008

Re: Subpoena in In re National Prescription Opiate Litig., MDL No. 2804

(N.D. Ohio)

Dear Mr. Mapes:

ENU MAINIGI

(202) 434-5420

emainigi@wc.com

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Sincerely,

/s/ Enu Mainigi
Enu Mainigi

UNITED STATES DISTRICT COURT

for the

		rict of Ohio	
In re: National Prescription Plaintiff v.)	ding in another district, state where:
Defendan.	t .))
SUBPO	ENA TO TESTIFY AT A D	DEPOSITION IN A C	CIVIL ACTION
To: Michael Mapes, 3510 Ho	llycrest Dr, Colorado Springs	, CO 80920-3008	
leposition to be taken in this ci	ivil action. If you are an orga or managing agents, or desig those set forth in an attachme	nization that is <i>not</i> a p mate other persons wh	place set forth below to testify at a party in this case, you must designate o consent to testify on your behalf
,			8/6/2018, 9:00AM
☐ Production: You, or y		o oring with jour to the	11
electronically stored in material:	formation, or objects, and pe	rmit their inspection, o	copying, testing, or sampling of the
electronically stored in material: The provisions of Fed. 5 (d) and (e), relating to your	formation, or objects, and pe R. Civ. P. 45(c), relating to	rmit their inspection, o	erson subject to a subpoena, and Rule consequences of not doing so, are
electronically stored in material: The provisions of Fed. 15 (d) and (e), relating to your attached. Date: 07/10/2018	formation, or objects, and pe R. Civ. P. 45(c), relating to	your protection as a personal and the potential of	erson subject to a subpoena, and Rule consequences of not doing so, are
electronically stored in material: The provisions of Fed. 15 (d) and (e), relating to your attached. Date: 07/10/2018	R. Civ. P. 45(c), relating to y	your protection as a persona and the potential of COURT	copying, testing, or sampling of the erson subject to a subpoena, and Rule

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

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•	r (name of individual and title, if any)		···
☐ I served the su	abpoena by delivering a copy to the nar	ned individual as follows:	
		on (date) ; or	
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		States, or one of its officers or agents, Ind the mileage allowed by law, in the am	
\$	•		
y fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under p	enalty of perjury that this information i	s true.	
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- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- (A) When Required. On timely motion, the issuing court must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- **(B)** When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information;
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or
- (iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

- (1) Producing Documents or Electronically Stored Information.

 These procedures apply to producing documents or electronically stored information:
- **(A)** *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- **(B)** Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
- **(C)** Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.
- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

- **(A)** *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 62 of 154. PageID #: 18787

EXHIBIT H

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W. WASHINGTON, D. C. 20005-5901 (202) 434-5000

FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

(202) 434-5420 emainigi@wc.com

ENU MAINIGI

July 10, 2018

By Federal Express and Electronic Mail

Dr. Christine Sannerud 10 Broadridge Ln Lutherville Timonium, MD 21093-1541

> Subpoena in In re National Prescription Opiate Litig., MDL No. 2804 Re: (N.D. Ohio)

Dear Dr. Sannerud:

I write on behalf of Defendants in the matter of In re National Prescription Opiate Litigation, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ Touhy regulations and the involvement of the United States Attorney for the Northern District of Ohio, see 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning this subpoena or require additional information.

> /s/ Enu Mainigi Enu Mainigi

Sincerely,

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

In re: National Prescription Opiate Litigation	
Plaintiff) Civil Action No. 1:17-md-02804-DAP
v.) CIVII ACTION No. 1.17-IIId-02004-DAI
	(If the action is pending in another district, state where:
Defendant	<u> </u>
SUBPOENA TO TESTIFY	AT A DEPOSITION IN A CIVIL ACTION
o: Christine Sannerud, 10 Broadridge Ln, Luther	ville Timonium, MD 21093-1541
eposition to be taken in this civil action. If you are	o appear at the time, date, and place set forth below to testify at a e an organization that is <i>not</i> a party in this case, you must designate or designate other persons who consent to testify on your behalf attachment:
Place: 725 Twelfth St. NW, Washington, D.C. 2000	Date and Time:
idee. The fireman entries, tractiming only have	08/08/2018, 9:00AM
☐ Production: You, or your representatives, 1	hod: Stenographic and/or by video and audio recording
☐ Production: You, or your representatives, relectronically stored information, or objects	hod: Stenographic and/or by video and audio recording must also bring with you to the deposition the following documents
☐ Production: You, or your representatives, relectronically stored information, or objects material: The provisions of Fed. R. Civ. P. 45(c), related and (e), relating to your duty to respond to the	thod: Stenographic and/or by video and audio recording must also bring with you to the deposition the following documents, and permit their inspection, copying, testing, or sampling of the
☐ Production: You, or your representatives, relectronically stored information, or objects material: The provisions of Fed. R. Civ. P. 45(c), relating to your duty to respond to the tached.	hod: Stenographic and/or by video and audio recording must also bring with you to the deposition the following documents s, and permit their inspection, copying, testing, or sampling of the
☐ Production: You, or your representatives, relectronically stored information, or objects material: The provisions of Fed. R. Civ. P. 45(c), relating to your duty to respond to the tached.	hod: Stenographic and/or by video and audio recording must also bring with you to the deposition the following documents s, and permit their inspection, copying, testing, or sampling of the ating to your protection as a person subject to a subpoena, and Rule is subpoena and the potential consequences of not doing so, are
☐ Production: You, or your representatives, relectronically stored information, or objects material: The provisions of Fed. R. Civ. P. 45(c), relating to your duty to respond to the tached.	hod: Stenographic and/or by video and audio recording must also bring with you to the deposition the following documents a, and permit their inspection, copying, testing, or sampling of the ating to your protection as a person subject to a subpoena, and Rule is subpoena and the potential consequences of not doing so, are RKOF COURT OR
The provisions of Fed. R. Civ. P. 45(c), relations of the distribution of the standard of the	hod: Stenographic and/or by video and audio recording must also bring with you to the deposition the following documents s, and permit their inspection, copying, testing, or sampling of the ating to your protection as a person subject to a subpoena, and Rule is subpoena and the potential consequences of not doing so, are OR /s/ Enu Mainigi
The provisions of Fed. R. Civ. P. 45(c), relating to your duty to respond to the tached. ate:07/10/2018	hod: Stenographic and/or by video and audio recording must also bring with you to the deposition the following documents and permit their inspection, copying, testing, or sampling of the string to your protection as a person subject to a subpoena, and Rule alis subpoena and the potential consequences of not doing so, are OR /s/ Enu Mainigi
The provisions of Fed. R. Civ. P. 45(c), relating to your duty to respond to the tached. ate:	hod: Stenographic and/or by video and audio recording must also bring with you to the deposition the following documents s, and permit their inspection, copying, testing, or sampling of the ating to your protection as a person subject to a subpoena, and Rule is subpoena and the potential consequences of not doing so, are **RKOF COURT** OR** S Enu Mainigi Deputy Clerk** Attorney's signature**

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena fo	r (name of individual and title, if any)		
s received by me on (d	ate)		
☐ I served the su	ubpoena by delivering a copy to the nan	ned individual as follows:	
		on (date) ; or	
☐ I returned the	subpoena unexecuted because:		
		States, or one of its officers or agents, I ad the mileage allowed by law, in the am	
\$	•		
fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under p	enalty of perjury that this information is	s true.	
•			
te:		Server's signature	AAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA
		Del vel B bigliature	
		Printed name and title	
	***************************************	Server's address	

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- **(A)** When Required. On timely motion, the issuing court must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- **(B)** When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information;
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or
- (iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
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(2) Claiming Privilege or Protection.

- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- **(e)** Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 67 of 154. PageID #: 18792

EXHIBIT I

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Mr. Matthew Strait 13485 Edge Rock Ct Chantilly, VA 20151-4102

Re: Subpoena in *In re National Prescription Opiate Litig.*, MDL No. 2804

(N.D. Ohio)

Dear Mr. Strait:

ENU MAINIGI

(202) 434-5420

emainigi@wc.com

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning this subpoena or require additional information.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi

UNITED STATES DISTRICT COURT

for the

Northern	n District of Ohio
In re: National Prescription Opiate Litigation Plaintiff v. Defendant SUBPOENA TO TESTIFY A	Civil Action No. 1:17-md-02804-DAP (If the action is pending in another district, state where:) TA DEPOSITION IN A CIVIL ACTION
To: Matthew Strait, 13485 Edge Rock Ct, Chantilly, \	
deposition to be taken in this civil action. If you are ar	ppear at the time, date, and place set forth below to testify at a n organization that is <i>not</i> a party in this case, you must designate designate other persons who consent to testify on your behalf achment:
Place: 725 Twelfth St. NW, Washington, D.C. 20005	Date and Time:
	08/08/2018, 9:00AM
material:	nd permit their inspection, copying, testing, or sampling of the
The provisions of Fed. R. Civ. P. 45(c), relating 45 (d) and (e), relating to your duty to respond to this attached.	ng to your protection as a person subject to a subpoena, and Rule subpoena and the potential consequences of not doing so, are
Date:07/10/2018	COF COURT OR /s/ Enu Mainigi
Signature of Clerk or Dep	
The name, address, e-mail, and telephone number of the All Defendants Enu Mainigi, 725 Twelfth St. NW, Washington, DC 2000	, who issues or requests this subpoena, are:

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for	(name of individual and title, if any)		
as received by me on (da	te)·		
☐ I served the su	bpoena by delivering a copy to the nam	ned individual as follows:	
		on (date) ;	or
☐ I returned the s	subpoena unexecuted because:		
	ena was issued on behalf of the United tness fees for one day's attendance, an	_	
\$	•		
y fees are \$	for travel and \$	for services, for a total o	f\$0.00
I declare under pe	nalty of perjury that this information i	s true.	
re:		Server's signature	
		server s signature	
		Printed name and title	
		Server's address	

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

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- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
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EXHIBIT J

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Ms. Michele Leonhart 2403 Voorhees Ave A Redondo Beach, CA 90278-2535

Re: Subpoena in In re National Prescription Opiate Litig., MDL No. 2804

(N.D. Ohio)

Dear Ms. Leonhart:

ENU MAINIGI

(202) 434-5420

emainigi@wc.com

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning this subpoena or require additional information.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

	cription Opiate Litigation))
Pi	laintiff)) Civil Action No. 1:17-md-02804-DAP
	v.)	Civil Action No. 1.17-mu-02804-DAP
	Ś	(If the action is pending in another district, state where:
Dej	fendant))
SU	BPOENA TO TESTIFY AT A D	EPOSITION IN A CIVIL ACTION
To: Michele Leonhart, 2	403 Voorhees Ave A, Redondo Be	ach, CA 90278-2535
deposition to be taken in to one or more officers, dire	this civil action. If you are an organ	at the time, date, and place set forth below to testify at a nization that is <i>not</i> a party in this case, you must designate nate other persons who consent to testify on your behalf ent:
Place: 725 Twelfth St. N	W, Washington, D.C. 20005	Date and Time:
Trace. 720 Twomar St. 10	111, 11a 2000	08/17/2018, 9:00AM
material:		
45 (d) and (e), relating to		our protection as a person subject to a subpoena, and Rule ena and the potential consequences of not doing so, are
attached.		
	SANDY OPACICH, CLERK OF C	OR
		OR /s/ Enu Mainigi
	SANDY OPACICH, CLERK OF C	OR/s/ Enu Mainigi
Date: <u>07/10/2018</u>	Signature of Clerk or Deputy Cler	OR /s/ Enu Mainigi Attorney's signature
		OR /s/ Enu Mainigi Attorney's signature

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for	(name of individual and title, if any)		
as received by me on (date	e)		
☐ I served the sub	poena by delivering a copy to the nar	med individual as follows:	
		on (date) ; or	
☐ I returned the su	ubpoena unexecuted because:		
<u>=</u>		States, or one of its officers or agents, and the mileage allowed by law, in the ar	
\$	<u> </u>		
y fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under pen	nalty of perjury that this information i	s true.	
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		20,10, 20,0,000	
		Printed name and title	
		-	

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

- (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction which may include lost earnings and reasonable attorney's fees on a party or attorney who fails to comply.
 - (2) Command to Produce Materials or Permit Inspection.
- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
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- (A) When Required. On timely motion, the issuing court must quash or modify a subpoena that:
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- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
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- (i) disclosing a trade secret or other confidential research, development, or commercial information;
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- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
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Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 77 of 154. PageID #: 18802

EXHIBIT K

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

ENU MAINIGI (202) 434-5420 emainigi@wc.com

July 10, 2018

By Federal Express and Electronic Mail

Mr. Keith Martin

Re: Subpoena in In re National Prescription Opiate Litig., MDL No. 2804

(N.D. Ohio)

Dear Mr. Martin:

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition.

Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning this subpoena or require additional information.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi

UNITED STATES DISTRICT COURT

for the

		Northern I	District of	Ohio
To: Keith Martin Testimony: YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is not a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment: Place: 725 Twelfth St. NW, Washington, D.C. 20005 Date and Time: 08/16/2018, 9:00AM The deposition will be recorded by this method: Stenographic and/or by video and audio recording Production: You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material: The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached. Date:07/10/2018 SANDY OPACICH, CLERK OF COURT OR Isl Enu Mainigi Signature of Clerk or Deputy Clerk Attorney's signature The name, address, e-mail, and telephone number of the attorney representing (name of party) All Defendants , who issues or requests this subpoena, are:	Plain V.	tiff)	
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All Defendants , who issues or requests this subpoena, are:		Signature of Clerk or Deputy	Clerk	·····
Enu Mainigi, 725 Twelfth St. NW, Washington, DC 20005, emainigi@wc.com, 202-434-5000	All Defendants			, who issues or requests this subpoena, are:

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

-	r (name of individual and title, if any)		
as received by me on (de	ate)		
☐ I served the su	abpoena by delivering a copy to the name	ned individual as follows:	
		on (date) ; or	· · · · · · · · · · · · · · · · · · ·
	auluma ama vimavva auto d'hanavvaa		
		States, or one of its officers or agents, I d the mileage allowed by law, in the am	
\$	•		
fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under pe	enalty of perjury that this information i	s true.	
te:		Server's signature	
		Printed name and title	
		Server's address	<u></u>

Additional information regarding attempted service, etc:

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EXHIBIT L

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

(202) 434-5420 emainigi@wc.com

ENU MAINIGI

July 10, 2018

By Federal Express and Electronic Mail

Mr. Gregory Brodersen

Re: Subpoena in *In re National Prescription Opiate Litig.*, MDL No. 2804 (N.D. Ohio)

Dear Mr. Brodersen:

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Sincerely,

/s/ Enu Mainigi
Enu Mainigi

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action

· . 85.

UNITED STATES DISTRICT COURT

for the

hio
ivil Action No. 1:17-md-02804-DAP f the action is pending in another district, state where:) TION IN A CIVIL ACTION
me, date, and place set forth below to testify at a that is <i>not</i> a party in this case, you must designate her persons who consent to testify on your behalf
Date and Time: 08/17/2018, 9:00AM
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with you to the deposition the following documents, ir inspection, copying, testing, or sampling of the
tection as a person subject to a subpoena, and Rule the potential consequences of not doing so, are
OR /s/ Enu Mainigi
Attorney's signature

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

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	late)·		
	ubpoena by delivering a copy to the nar		
		on (date) ; or	
☐ I returned the	subpoena unexecuted because:		W
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y fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under r	penalty of perjury that this information	is true.	
1			
ate:		Server's signature	
		Printed name and title	

Additional information regarding attempted service, etc:

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EXHIBIT M

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.

ENU MAINIGI (202) 434-5420 emainigi@wc.com WASHINGTON, D. C. 20005-5901 (202) 434-5000 FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Ms. Denise Foster

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(N.D. Ohio)

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Sincerely,

/s/ Enu Mainigi

Enu Mainigi

UNITED STATES DISTRICT COURT

for the

	Northern I	District of	Ohio
Pl	cription Opiate Litigation aintiff v. fendant	j	Civil Action No. 1:17-md-02804-DAP If the action is pending in another district, state where:
SU	BPOENA TO TESTIFY AT	A DEPOS	ITION IN A CIVIL ACTION
To: Denise Foster	•		
deposition to be taken in to one or more officers, dire	this civil action. If you are an o	organizatio esignate of	time, date, and place set forth below to testify at a in that is <i>not</i> a party in this case, you must designate ther persons who consent to testify on your behalf
Place: 725 Twelfth St. N	IW, Washington, D.C. 20005		Date and Time:
			08/16/2018, 9:00AM
☐ Production: You	, or your representatives, must	also bring	with you to the deposition the following documents, eir inspection, copying, testing, or sampling of the
			otection as a person subject to a subpoena, and Rule d the potential consequences of not doing so, are
Date: 07/10/2018	SANDY OPACICH, CLERK C	OF COURT	OR /s/ Enu Mainigi
	Signature of Clerk or Deputy	Clerk	Attorney's signature
All Defendants	il, and telephone number of the		, who issues or requests this subpoena, are:
	, 5,	J (-

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for us received by me on (da	(name of individual and title, if any)te) .		
		ned individual as follows:	
		on (date) · or	
	ubpoena unexecuted because:		
		_	
		, ,	
fees are \$	for travel and \$	ng a copy to the named individual as follows: on (date) ; or ted because: behalf of the United States, or one of its officers or agents, I have day's attendance, and the mileage allowed by law, in the amount avel and \$ for services, for a total of \$ at this information is true. Server's signature Printed name and title	0.00
I declare under ne	nalty of naviywy that this information i	g two	
i declare under pe	manty of perjury that this information is	s u ue.	
e:			***************************************
		Server's signature	
	***************************************	Printed name and title	

		Server's address	

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- **(A)** When Required. On timely motion, the issuing court must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- **(B)** When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information;
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or
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- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
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- (1) *Producing Documents or Electronically Stored Information*. These procedures apply to producing documents or electronically stored information:
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- **(A)** *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
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- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Case: 1:17-md-02804-DAP Doc #: 789-1 Filed: 07/25/18 92 of 154. PageID #: 18817

EXHIBIT N

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Mr. Derek Siegle 5082 W 5th St Unit W Independence, OH 44131-1125

Re: Subpoena in *In re National Prescription Opiate Litig.*, MDL No. 2804

(N.D. Ohio)

Dear Mr. Siegle:

ENU MAINIGI

(202) 434-5420

emainigi@wc.com

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for your appearance at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning this subpoena or require additional information.

Sincerely,

/s/ Enu Mainigi

Enu Mainigi

UNITED STATES DISTRICT COURT

for the

Northern District	of Ohio
In re: National Prescription Opiate Litigation) Plaintiff) V.) Defendant)	Civil Action No. 1:17-md-02804-DAP (If the action is pending in another district, state where:
SUBPOENA TO TESTIFY AT A DEP	OSITION IN A CIVIL ACTION
To: Derek Siegle, 5082 W 5th St Unit W, Independence, OH 4	14131-1125
Testimony: YOU ARE COMMANDED to appear at the deposition to be taken in this civil action. If you are an organization one or more officers, directors, or managing agents, or designate about the following matters, or those set forth in an attachment:	ation that is <i>not</i> a party in this case, you must designate e other persons who consent to testify on your behalf
Place: 725 Twelfth St. NW, Washington, D.C. 20005	Date and Time: 08/15/2018
The deposition will be recorded by this method: Sten Production: You, or your representatives, must also br electronically stored information, or objects, and permit material:	ing with you to the deposition the following documents,
The provisions of Fed. R. Civ. P. 45(c), relating to your 45 (d) and (e), relating to your duty to respond to this subpoena attached.	r protection as a person subject to a subpoena, and Rule and the potential consequences of not doing so, are
Date: 07/10/2018 SANDY OPACICH, CLERK OF COL	<i>URT</i> OR /s/ Enu Mainigi
Signature of Clerk or Deputy Clerk	Attorney's signature
The name, address, e-mail, and telephone number of the attorned All Defendants Enu Mainigi, 725 Twelfth St. NW, Washington, DC 20005, emain	, who issues or requests this subpoena, are:

18.

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

.. 22%

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

•	t (name of individual and title, if any)		
s received by me on (do	nte)		
☐ I served the su	bpoena by delivering a copy to the nar	ned individual as follows:	
		on (date) ; or	
☐ I returned the	subpoena unexecuted because:		
		States, or one of its officers or agents, and the mileage allowed by law, in the ar	
\$	•		
fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under pe	enalty of perjury that this information i	s true.	
•			
e:		Community and an artists	
		Server's signature	
		Printed name and title	
		Server's address	

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

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EXHIBIT O

LAW OFFICES

WILLIAMS & CONNOLLY LLP

725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
(202) 434-5000
FAX (202) 434-5029

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

July 10, 2018

By Federal Express and Electronic Mail

Drug Enforcement Administration 8701 Morrissette Dr. Springfield, VA 22152

Re: Subpoenas in *In re National Prescription Opiate Litig.*, MDL No. 2804 (N.D. Ohio)

To whom it may concern:

ENU MAINIGI

(202) 434-5420

emainigi@wc.com

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Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

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Sincerely,

/s/ Enu Mainigi
Enu Mainigi

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

	Northern Di	istrict of	Ohio	
Pl	cription Opiate Litigation laintiff V. fendant	j	Civil Action No. 1:17-md-02804-DAP (If the action is pending in another district, state v	vhere:)
SU	BPOENA TO TESTIFY AT A	DEPOS	SITION IN A CIVIL ACTION	
To: Drug Enforcement A	Administration, 8701 Morrissette	Dr., Spri	ingfield, VA 22152	
deposition to be taken in to one or more officers, direct	this civil action. If you are an or	ganization signate of	time, date, and place set forth below to te on that is <i>not</i> a party in this case, you must other persons who consent to testify on yo	st designate
Place: Williams & Conno			Date and Time:	
725 Twelfth St. N	IW, Washington, D.C. 20005		9:00AM, 08/21/2018	
☐ Production: You	i, or your representatives, must a	lso bring	g with you to the deposition the following neir inspection, copying, testing, or sample	documents,
		poena an	rotection as a person subject to a subpoend the potential consequences of not doing	
			/s/ Enu Mainigi	
	Signature of Clerk or Deputy (Clerk	Attorney's signature	

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

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This subpoena for vas received by me on (da				
☐ I served the su	bpoena by delivering a copy to the nar	med individual as follows:		
		on (date)	; or	
☐ I returned the s	subpoena unexecuted because:			
	ena was issued on behalf of the United tness fees for one day's attendance, ar		•	
\$	·			
y fees are \$	for travel and \$	for services, for	a total of \$	0.00
I declare under pe	enalty of perjury that this information i	s true.		
ate:				
		Server's signatur	re	
		Printed name and	title	
		Server's addres.	S	

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SCHEDULE A

DEFINITIONS

The following terms shall have the meanings set forth below. Other terms shall have their plain meaning.

- 1. "You" and "Your" refers to the Drug Enforcement Administration ("DEA") and all others acting or purporting to act on DEA's behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.
- 2. "Communication" means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
- 3. "Defendants" means all defendants named in *In re National Prescription Opiate Litig.*, MDL No. 2804, as of the date of this notice.
- 4. "Prescription Opioids" means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in Ohio only through prescriptions filled by dispensers duly licensed and regulated.
- 5. "Illicit Opioids" means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted
- 6. "DEA Registrant" means Registrant as defined in 21 CFR 1300.01(b) ("any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act").
- 7. "Chargeback Data" means information that a manufacturer receives from a distributor in connection with a chargeback, a contractual payment from a manufacturer to a distributor made after a distributor sells the manufacturer's product to the distributor's customer for less than the price the distributor paid the manufacturer for the product.
- 8. "Prescriber Data" means all information related to a person or entity that writes or has written a prescription as defined in 21 CFR. 1300.01(b) ("Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user...").
- 9. "Suspicious Order Report" means a report filed by DEA Registrants pursuant to 21 CFR 1301.74(b).

- 10. "ARCOS Data" means data reported by DEA Registrants pursuant to 21 U.S.C. § 827 through the Automation of Reports and Consolidated Orders System.
- 11. "Opioid Production Quota" means the quantity of Prescription Opioids "necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks" per 21 C.F.R 1303.11.
- 12. "Opioid Procurement Quota" means the quantity of Prescription Opioids that DEA allows a person or entity to "procure and use... for the purpose of manufacturing such class into dosage forms or into other substances per 21 CFR 1303.12.

TOPICS FOR EXAMINATION

The topics upon which the person or persons designated by You are asked to be prepared to testify in accordance with Rule 30(b)(6) are:

- 1. The organizational structure of the Office of Diversion Control and the Detroit Diversion Office, the Cleveland, OH Resident Office, the Youngstown, OH Resident Office, the Cleveland Tactical Diversion Squad, and any other unit or subunit of DEA with responsibilities in the state of Ohio.
- 2. Your interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.
- 3. Guidance or other Communications provided by You to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74.
- 4. Your involvement in lawsuits brought against DEA-registered distributors by customers whose orders of controlled substances had been blocked based on the distributor's determination that the orders were "suspicious" pursuant to 21 C.F.R. § 1301.74, or whose ability to purchase controlled substances had been denied or terminated.
- 5. Your interpretation, enforcement, and practices regarding any obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.
- 6. The use or potential use of Prescriber Data in connection with any obligation under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.
- 7. Your efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio.
- 8. Inquiries or complaints received by You from any government officials of the Ohio Board of Pharmacy, the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or

- Cuyahoga County regarding Suspicious Order Reports, or suspected or actual diversion of Prescription Opioids.
- 9. Your procedures and practices relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS Data, Suspicious Order Reports, or other Communications from DEA Registrants to identify and stop sources of diversion.
- 10. Investigations or inquiries by You concerning the Defendants.
- 11. Your practice of notifying DEA-registered distributors when another distributor terminated its relationship with a customer due to the risk of diversion, including DEA's decision to discontinue such practice.
- 12. Your decision not to allow DEA-registered distributors access to de-identified ARCOS Data prior to February 2018, and its decision to provide DEA-registered distributors with limited access to certain ARCOS Data in February 2018.
- 13. Your practices and procedures relating to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids.
- 14. The basis for Opioid Procurement Quotas and Opioid Production Quotas of Prescription Opioids from 1995 to 2018.
- 15. Your procedures, process, approach, and criteria used to determine the legitimate medical, scientific, and industrial needs for Prescription Opioids and setting Opioid Production Quotas based upon those determinations.
- 16. Communications between You and any of the Defendants.
- 17. Communications between You and the Board of Pharmacy of any State, the Attorney General of any State, or government officials of the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County relating to Prescription Opioids or Illicit Opioids.
- 18. Your policies, procedures, practices, and experience regarding the sharing of ARCOS data with state and local law enforcement entities when requested by them in connection with investigations of or suspicions regarding possible diversion by DEA-registrants in their jurisdictions.
- 19. Your policies and procedures relating to the "High Intensity Drug Trafficking Areas" (HIDTA) program.
- 20. The HIDTA program's efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County.

- 21. Your Communications relating to and efforts to comply with the reports and recommendations contained in the following GAO Reports:
 - a. Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed: Coordination between DEA and FDA Should Be Improved, GAO-15-202 (Washington, D.C.: February 2, 2015);
 - b. Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access, GAO-15-471 (Washington, D.C.: June 25, 2015);
 - c. Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations, GAO-16-737T (Washington, D.C.: June 22, 2016).
- 22. Your expenditure of funds allocated to the Diversion Control Fee Account.
- 23. Your process for licensing prescribers of controlled substances.
- 24. Investigation into the retention or removal of documents by Joseph Rannazzisi, and any other former DEA employees currently retained by Plaintiffs.

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

.150

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

In re National Prescription Opiate Litigation	
Plaintiff	_)
v.	Civil Action No. 1:17-md-02804-DAP
Defendant	-))
	CUMENTS, INFORMATION, OR OBJECTS ON OF PREMISES IN A CIVIL ACTION
To: Drug Enforcement Administrati	ion, 8701 Morrissette Dr., Springfield, VA 22152
(Name of perso	on to whom this subpoena is directed)
	oroduce at the time, date, and place set forth below the following ts, and to permit inspection, copying, testing, or sampling of the er #2
Place: Williams & Connolly LLP, 725 Twelfth St. NW,	Date and Time:
Washington, DC 20005	07/31/2018 9:30 am
other property possessed or controlled by you at the tin may inspect, measure, survey, photograph, test, or same Place:	me, date, and location set forth below, so that the requesting party uple the property or any designated object or operation on it. Date and Time:
The following provisions of Fed. R. Civ. P. 45 Rule 45(d), relating to your protection as a person subjrespond to this subpoena and the potential consequence Date: 07/10/2018	5 are attached – Rule 45(c), relating to the place of compliance; ject to a subpoena; and Rule 45(e) and (g), relating to your duty to ses of not doing so.
CLERK OF COURT	
	OR
Signature of Clerk or Dep	/s/ Enu Mainigi uty Clerk Attorney's signature
The name, address, e-mail address, and telephone num	ther of the attorney representing (name of party)
The name, address, e-man address, and telephone num All Defendants	, who issues or requests this subpoena, are:
Enu Mainigi, 725 Twelfth St. NW, Washington, DC 200	
End wanigh, 720 Twoner Ct. 1444, 44doinington, DO 200	, 500, 511.611.191.6511, 202 101 0000

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this su	abpoena for (name of individual and title, if a	ny)	
(date)	·		
☐ I served the s	ubpoena by delivering a copy to the nat	med person as follows:	
		on (date) ;	or
☐ I returned the	subpoena unexecuted because:		
		States, or one of its officers or agents, I e, and the mileage allowed by law, in the	
\$	•		
fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under p	penalty of perjury that this information is	is true.	
·-			
e:		Server's signature	
		Printed name and title	
		Server's address	

Additional information regarding attempted service, etc.:

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action(Page 3)

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

- (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
- (ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
 - (B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information; or

- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
 - (ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

- (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
- (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
- (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.
- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

DEFINITIONS

Notwithstanding any definition set forth below, each word, term, or phrase used in these Requests is intended to have the broadest meaning permitted under the Federal Rules of Civil Procedure and the Local Civil Rules for the District Court of the Northern District of Ohio.

- 1. "You" and "Your" refers to the Drug Enforcement Administration ("DEA") and all others acting or purporting to act on DEA's behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.
- 2. "Communication" means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
- 3. "Defendants" means all defendants named in *In re National Prescription Opiate Litig.*, MDL No. 2804, as of the date of this notice.
- 4. "Document" has the full meaning ascribed to it by Federal Rule of Civil Procedure 34(a), and means the complete original (or complete copy where the original is unavailable) and each non-identical copy (where different from the original because of notes made on the copy or otherwise) of any writing or record, including, but not limited to, all written, typewritten, handwritten, printed, or graphic matter of any kind or nature, however produced or reproduced, any form of collected data for use with electronic data processing equipment, and any mechanical or electronic visual or sound recordings or text messages in Your possession, custody, or control. "Documents" include, but are not limited to, books, papers, contracts, memoranda, invoices, correspondence, notes, studies, reports, manuals, photographs, drawings, charts, graphs, data compilations, other writings, microfilm, microfiche, audio recordings, video recordings, electronic mail, and any other information stored in electronic form, and each different version or copy of each Document, including, but not limited to, drafts.
- 5. "Prescription Opioids" means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in Ohio only through prescriptions filled by dispensers duly licensed and regulated.
- 6. "Illicit Opioids" means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted.

- 7. "DEA Registrant" means Registrant as defined in 21 CFR 1300.01(b) ("any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act").
- 8. "Registration" means Registration as defined in 21 CFR 1300.01(b) ("registration required and permitted by sections 303 or 1007 of the [Controlled Substances] Act").
- 9. "Chargeback Data" means information that a manufacturer receives from a distributor in connection with a chargeback, a contractual payment from a manufacturer to a distributor made after a distributor sells the manufacturer's product to the distributor's customer for less than the price the distributor paid the manufacturer for the product.
- 10. "Prescriber Data" means all information related to a person or entity that writes or has written a prescription as defined in 21 CFR. 1300.01(b) ("Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user...").
- 11. "Opioid Production Quota" means the quantity of Prescription Opioids "necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks" per 21 C.F.F 1303.11.
- 12. "Opioid Procurement Quota" means the quantity of Prescription Opioids that DEA allows a person or entity to "procure and use... for the purpose of manufacturing such class into dosage forms or into other substances per 21 CFR 1303.12.
- 13. "Suspicious Order Monitoring Program" means a system intended to aid in compliance with 21 CFR. 1301.74 as defined by DEA to be required by 21 CFR. 1301.74.

INSTRUCTIONS

Should You consider any of the Documents requested to be confidential such that they should not be generally disseminated to the public or released to the press, we ask that You designate them as such under the Protective Order in the MDL (copy attached) and the parties will deal with them accordingly.

All of the following requests are intended to encompass Documents maintained in electronic or paper form, and "correspondence" or "Communications" include emails, letters or other papers, and memos reflecting oral Communications.

As these Documents will be shared with a large number of counsel and parties, we ask that You produce copies of them in electronic or paper form. Please let the undersigned know if there are charges or fees for searching or copying and, if so, also advise whether You will provide an invoice for the cost after production or if prepayment is required.

Unless otherwise indicated, the Relevant Time Period applicable to these requests is 1996 to the present.¹

DOCUMENTS TO BE PRODUCED

- 1. All Documents concerning Communications between DEA and DEA Registrants regarding any actual or purported obligation under 21 U.S.C. § 823, 21 CFR 1301.74 or any other DEA regulation with respect to suspicious orders for controlled substances, including but not limited to letters, presentations, emails, conference materials, or other correspondence.
- 2. All Documents concerning DEA's ability or willingness to provide guidance to DEA Registrants regarding their obligations under 21 U.S.C. § 823, 21 CFR 1301.74, or any other DEA regulation with respect to suspicious orders for controlled substances.
- 3. All Documents concerning the meaning of the term "suspicious orders" in connection with orders for controlled substances, including but not limited to all Documents reflecting DEA's position regarding the meaning of "suspicious orders."
- 4. All Documents concerning any requirement or expectation that DEA Registrants inform DEA of suspicious orders not placed directly with the Registrant, such as orders exchanged between two third parties.
- 5. All Documents concerning the use or potential use of Chargeback Data in connection with any obligation under the CSA, 21 CFR 1301.74, or any other DEA regulation, including but not limited to all Documents regarding DEA's position on whether DEA Registrants had a legal duty to review such data.
- 6. All Documents concerning the use or potential use of Prescriber Data in connection with any obligation under the CSA, 21 CFR 1301.74, or any other DEA regulation, including but not limited to all Documents regarding DEA's position on whether DEA Registrants had a legal duty to review such data.
- 7. All Documents reflecting or related to DEA's position regarding any obligation of DEA Registrants to halt or not ship suspicious orders.
- 8. All Documents constituting or describing DEA's procedures, policies, or protocols regarding its receipt, organization, analysis, utilization, and handling of suspicious order reports received pursuant to 21 CFR 1301.74.
- 9. All Documents describing, relating to, or reflecting efforts made by DEA to utilize the ARCOS data, suspicious order reports, and/or other communications from Defendants to

¹ Defendants have asserted that discovery in this matter should be limited to the relevant statutes of limitations for Plaintiffs claims. Thus far, the Court has determined that the relevant time period goes back to at least 1996. Should the Court issue a ruling establishing a different time period for discovery, we will revise the Relevant Time period accordingly.

- identify pharmacists, pharmacy interns, doctors or other prescribers, or patients who might be diverting controlled substances.
- 10. All Documents describing, relating to, or reflecting Defendants' efforts to obtain access to ARCOS data and/or suspicious order reports to identify pharmacists, pharmacy interns, doctors or other prescribers, or patients who might be diverting controlled substances including, but not limited to, all Documents describing, relating to, or reflecting the DEA's response to Defendants' efforts to obtain access to ARCOS data and/or suspicious order reports.
- 11. All DEA files and records relating to diversion or misuse of Prescription Opioids, including but not limited to the following:
 - a. Correspondence related to potential or actual diversion or misuse of Prescription Opioids;
 - b. Correspondence from or to any other Department of Justice agency or office (including but not limited to, any United States Attorney's Office), any other federal agency, any state agency, or any federal, state, or local official relating to the diversion or misuse of Prescription Opioids;
 - c. Complaints made to DEA relating to the diversion or misuse of Prescription Opioids, documents and correspondence reflecting any actions undertaken by DEA relating to such complaints, and any other records relating to such complaints;
 - d. Correspondence with any federal, state, or local agency regarding Suspicious Order reports.
- 12. All Documents concerning DEA's efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio.
- 13. Organizational charts and other Documents reflecting the structure and operations of the Office of Diversion Control, the Detroit Division Office, the Cleveland, OH Resident Office, the Youngstown, OH Resident Office, the Cleveland Tactical Diversion Squad, and any other unit or subunit of DEA with responsibilities in the state of Ohio.
- 14. All Documents concerning policies and procedures related to the "High Intensity Drug Trafficking Areas" (HIDTA) program, including Documents regarding the criteria and process involved in designation of a HIDTA.
- 15. All Documents concerning any and all HIDTAs in the state of Ohio, and all Documents concerning DEA operations, activities, or assistance related to any and all HIDTAs in the state of Ohio.
- 16. All Documents concerning Communications between DEA and any other Department of Justice agency or office, the Office of National Drug Control Policy, and any other federal agency regarding strategies and proposals to address the opioid crisis.

- 17. All Documents reflecting or relating to reports, inquiries, or complaints received from any government officials of the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, regarding suspicious order reports pursuant to 21 CFR 1301.74, or suspected or actual diversion or misuse of Prescription Opioids by TDDDs, pharmacists, pharmacy interns, doctors, other prescribers or dispensers, or patients.
- 18. All Documents and Communications with any federal, state, or local agency in or with jurisdiction over the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, regarding efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic.
- 19. All Documents and Communications regarding any assistance or grants the DEA gave to any federal, state, or local agency in or with jurisdiction over the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic.
- 20. All Documents and Communications with any federal, state, or local agency in or with jurisdiction over the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, and/or any distributor or manufacturer, regarding access to Suspicious Order reports and/or the DEA's ARCOS database.
- 21. All Documents or Communications concerning the DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances
- 22. All Documents and Communications concerning the determination of Opioid Production Quotas and Opioid Procurement Quotas.
- 23. All Documents concerning Communications with or about the Healthcare Distribution Alliance or Healthcare Distribution Management Association.
- 24. All Documents concerning Communications with or about the Government Accountability Office (GAO) relating to the following reports:
 - a. Prescription Drugs: More DEA Information about Registrants' Controlled Substances Role Could Improve Their Understanding and Help Ensure Access, GAO-15-471 (June 25, 2015).

- b. Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved, GAO-15-202 (February 2, 2015).
- c. Additional Actions Needed to Address Prior GAO Recommendations, GAO-16-737T (June 22, 2016).
- 25. All Communications or correspondence between DEA and any of the Defendants.
- 26. All Documents concerning Communications with or regarding the Defendants, including but not limited to Communications regarding their Suspicious Order Monitoring Program, the adequacy of Defendants' systems to safeguard against diversion, Quota, or Prescription Opioids.
- 27. All Documents or Communications concerning the DEA's desire to receive suspicious order reports, including any and all Documents or Communications in which the DEA told a manufacturer or distributor to stop submitting suspicious order reports.
- 28. All Documents concerning any visits by DEA personnel to any of Defendants' facilities, including but not limited to reports regarding audits and inspections, audit work papers, check sheets, and questions or inquiries concerning suspicious order monitoring, detecting, and reporting.
- 29. All Documents concerning the DEA registration of any of the Defendants, including but not limited to all Documents describing, relating to, or reflecting the revocation of Registration for any DEA Registrant relating to Prescription Opioids.
- 30. All Documents concerning any investigation or inquiry by DEA concerning the Defendants.
- 31. Documents concerning any efforts to address the diversion of Prescription Opioids in the state of Ohio.
- 32. All Documents concerning this civil action (captioned above) or any other lawsuit (regardless of whether criminal or civil, and regardless of whether brought or pending in state or federal court in the United States) relating to the diversion, overprescribing, or misuse of Prescription Opioids.
- 33. All Documents DEA has identified or determined were retained by Joseph Rannazzisi upon the conclusion of his employment with DEA, as well as all documents concerning DEA's investigation of whether documents were retained by Mr. Rannazzisi upon the conclusion of his employment with DEA.
- 34. The complete personnel file relating to the employment of Joseph Rannazzisi by the DEA.

- 35. All Documents DEA has identified or determined were retained by Jim Geldof upon the conclusion of his employment with DEA, as well as all documents concerning DEA's investigation of whether documents were retained by Mr. Rannazzisi upon the conclusion of his employment with DEA.
- 36. The complete personnel file relating to the employment of Jim Geldof by the DEA.
- 37. All Documents provided by the DEA or by any current or former employee of the DEA to the Washington Post and/or to 60 Minutes, and all Documents concerning DEA's investigation relating to Documents provided to the Washington Post and/or 60 Minutes.

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EXHIBIT P

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 1 of 38. PageID #: 5799

IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE:	NATIONAL	PRESCRIP'	TION
OPIATE	ELITIGATIO	N	

Case No.: 1:17-md-2804-DAP

Honorable Dan Aaron Polster

This document relates to:

All Cases

CASE MANAGEMENT ORDER NO. _____ : PROTECTIVE ORDER

I. Scope of Order

- 1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Stipulated Protective Order ("Protective Order" or "Order"). Unless otherwise noted, this Order is also subject to the Local Rules of this District and the Federal Rules of Civil Procedure on matters of procedure and calculation of time periods. Unless otherwise stated, all periods of time provided for in this Order are calculated as calendar days
- 2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, captioned as *In re: National Prescription Opiate Litigation* (MDL No. 2804), Case No. 1:17-CV-2804, which includes any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned there ("the Litigation"). All materials produced or adduced in the course of

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 2 of 38. PageID #: 5800

discovery, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any Party to this Litigation (the "Producing Party") to any other party or parties (the "Receiving Party"). This Protective Order is binding upon all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

- 3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.
- 4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).
- 5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.
- 6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

II. Definitions

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7. Party. "Party" means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information and/or Highly Confidential

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Information as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

- 8. <u>Discovery Material</u>. "Discovery Material" means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) ("Computerized Material") is produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation.
- 9. <u>Competitor.</u> Competitor means any company or individual, other than the Designating Party, engaged in the design; development; manufacture; regulatory review process; dispensing; marketing; distribution; creation, prosecution, pursuit, or other development of an interest in protecting intellectual property; and/or licensing of any product or services involving opioids; provided, however, that this section shall not be construed as limiting the disclosure of Discovery Material to an Expert in this Litigation, so long as the notice required under Paragraph 38 is provided to the Designating Party prior to any such disclosure where required, and so long as no Discovery Material produced by one Defendant is shown to any current employee or consultant of a different Defendant,

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except as provided in Paragraphs 33 or 34.

- Confidential Information. "Confidential Information" is defined herein as 10. information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Health Information, protected law enforcement materials (including investigative files, overdose records, narcane, coroner's records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Confidential."
- 11. <u>Highly Confidential Information</u>. "Highly Confidential Information" is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective

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Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Highly Confidential."

- 12. <u>Manufacturer Defendant</u>: Manufacturer Defendant means any Defendant in this litigation that manufactures any Opioid Product for sale or distribution in the United States.
- 13. <u>Distributor Defendant</u>: Distributor Defendant means any Defendant in this litigation that distributes any Opioid Product in the United States other than a product they manufacture or license for manufacture.
- 14. Retail Defendant: Retail Defendant means any Defendant in this litigation that sells or distributes any Opioid Product directly to consumers in the United States.
- 15. Receiving Party. "Receiving Party" means a Party to this Litigation, and all employees, agents, and directors (other than Counsel) of the Party that receives Discovery Material from a Producing Party.
- 16. <u>Producing Party</u>. "Producing Party" means a Party to this Litigation, and all directors, employees, and agents (other than Counsel) of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to paragraph 3.
- 17. <u>Protected Material</u>. "Protected Material" means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as "Confidential" or "Highly Confidential" in accordance with this Protective Order.
 - 18. Outside Counsel. "Outside Counsel" means any law firm or attorney who

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represents any Party for purposes of this litigation.

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- 19. <u>In-House Counsel</u>. "In-House Counsel" means attorney employees of any Party.
- 20. <u>Counsel</u>. "Counsel," without another qualifier, means Outside Counsel and In- House Counsel.
- 21. <u>Independent Expert</u>. "Independent Expert" means an expert and/or independent consultant formally retained, and/or employed to advise or to assist Counsel in the preparation and/or trial of this Litigation, and their staff who are not employed by a Party to whom it is reasonably necessary to disclose Confidential Information or Highly Confidential Information for the purpose of this Litigation.
- 22. <u>This Litigation</u>. "This Litigation" means all actions in MDL No. 2804, *In re:* National Prescription Opiate Litigation or hereafter subject to transfer to MDL No. 2804.

III. Designation and Redaction of Confidential Information

- 23. For each document produced by the Producing Party that contains or constitutes Confidential Information or Highly Confidential Information pursuant to this Protective Order, each page shall be marked "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.
- 24. Specific discovery responses produced by the Producing Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.

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Information disclosed through testimony at a deposition taken in connection 25. with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL-SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed.

- 26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34, below, along with the witness and the witness's counsel may be present if any questions regarding Confidential Information or Highly Confidential are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.
- 27. A Party in this Litigation may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes

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qualifies as the designating Party's Confidential Information or Highly Confidential

Information pursuant to this Protective Order. The Party claiming confidentiality shall

designate the information as such within thirty (30) days of its receipt of such information.

Any Party receiving information from a third party shall treat such information as Highly

Confidential during this thirty (30) day period while all Parties have an opportunity to

review the information and determine whether it should be designated as confidential. Any

Party designating third party information as Confidential Information or Highly Confidential

Information shall have the same rights as a Producing Party under this Protective Order

with respect to such information.

28. This Protective Order shall not be construed to protect from production or to

permit the "Confidential Information" or "Highly Confidential Information" designation of any

document that (a) the party has not made reasonable efforts to keep confidential, or (b) is

at the time of production or disclosure, or subsequently becomes, through no wrongful act

on the part of the Receiving Party or the individual or individuals who caused the

information to become public, generally available to the public through publication or

otherwise.

29. In order to protect against unauthorized disclosure of Confidential

Information and Highly Confidential Information, a Producing Party may redact certain

Confidential or Highly Information from produced documents, materials or other things.

The basis for any such redaction shall be stated in the Redaction field of the metadata

produced pursuant to the Document Production Protocol or, in the event that such

metadata is not technologically feasible, a log of the redactions. Specifically, the

Producing Party may redact:

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- (i) <u>Personal Identifying Information</u>. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees' names and business contact information) and (b) individuals in clinical studies or adverse event reports whose identity is protected by law.
- (ii) <u>Privileged Information</u>. Information protected from disclosure by the attorney-client privilege, work product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.
- (iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce such documents in litigation.
- 30. To the extent any document, materials, or other things produced contain segregated, non-responsive Confidential or Highly Confidential Information concerning a Producing Party's non-opioid products (or, in the case of Plaintiffs, concerning programs, services, or agencies not at issue in this litigation), the Producing Party may redact that segregated, non-responsive, Confidential or Highly Confidential information except (a) that if a Producing Party's non-opioid product is mentioned in direct comparison to the Producing Party's opioid product, then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the Producing Party's non-opioid product(s) would render the information pertaining to Producing Party's opioid product meaningless or would remove the context of the information about

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Producing Party's opioid product, the name and information about the other product may not be redacted. Nothing in this paragraph shall restrict Plaintiffs' right and ability to request information about such other products nor restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

31. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients who were reported as experiencing adverse events that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as CONFIDENTIAL INFORMATION. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

IV. Access to Confidential and Highly Confidential Information

- 32. <u>General</u>. The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Confidential or Highly Confidential Information to any third person or entity except as set forth in Paragraphs 33 and 34.
- 33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.I) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:
 - a. Outside Counsel and In-House Counsel, and the attorneys, paralegals,
 stenographic, and clerical staff employed by such counsel;
 - b. Vendor agents retained by the parties or counsel for the parties, provided

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that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound:

- c. Individual Parties;
- d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;
- e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- h. Any individual(s) who authored, prepared, or previously reviewed or received the information;

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i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.

- j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;
- I. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification

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contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order.; or

- m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.
- 34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless

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that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel of any Plaintiff, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to one In-House counsel of another Defendant, provided that the In-House counsel (i) has regular involvement in the Litigation, (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the certification contained in **Exhibit** Α, individual completes the Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;
- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;;
- c. Individual Parties that have produced the designated information;
- d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

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f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

- g. Any individual(s) who authored, prepared or previously reviewed or received the information;
- h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;
- j. Counsel for claimants litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient

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agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant; or

- k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Highly Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Highly Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.
- 35. With respect to documents produced to Plaintiffs, documents designated as "HIGHLY CONFIDENTIAL" will be treated in the same manner as documents designated "CONFIDENTIAL," except that Plaintiffs may not disclose Highly Confidential Information to In-House Counsel (or current employees) of any Competitor of the Producing Party, except as otherwise provided in this Order or any other Order in this Litigation.

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36. In the event that In-House Counsel (or current employees) of any Competitor of the Producing Party is present at the deposition of an employee or former employee of the Producing Party, prior to a document designated as Highly Confidential being used in the examination, such In-House Counsel (current employees) of any Competitor of the Producing Party shall excuse himself or herself from the deposition room without delaying or disrupting the deposition.

V. Confidentiality Acknowledgment

Each person required under this Order to complete the certification 37. contained in Exhibit A, Acknowledgment and Agreement to Be Bound, shall be provided with a copy of this Protective Order, which he or she shall read, and, upon reading this Protective Order, shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Unless otherwise provided in this Order, Counsel for each Party shall maintain the Acknowledgments without giving copies to the other side. The Parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Confidential Information or Highly Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements, but must comply with the terms of this Protective Order.

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VI. Litigation Experts and Consultants.

- Formally Retained Independent Experts and Consultants. Subject to the 38. provisions of this Protective Order, all Confidential Information or Highly Confidential Information may be disclosed to any formally retained independent expert or consultant who has agreed in writing pursuant to Paragraph 37 or on the record of a deposition to be bound by this Protective Order. The party retaining an independent expert or consultant shall use diligent efforts to determine if the independent expert or consultant is currently working with or for a Competitor of a Producing Party in connection with a Competitor's opioid product. Prior to the initial disclosure of any information designated as Confidential Information or Highly Confidential Information to an expert or consultant who is currently working with or for a Competitor of the Producing Party in connection with a Competitor's opioid product, the party wishing to make such a disclosure ("Notifying Party") shall provide to counsel for the Producing Party in writing, which may include by e- mail, a statement that such disclosure will be made, identifying the general subject matter category of the Discovery Material to be disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the general purpose of such disclosure; the specific name of the formally retained independent expert or consultant need not be provided. The Producing Party shall have seven (7) days from its receipt of the notice to deliver to the Notifying Party its good faith written objections (if any), which may include e-mail, to such disclosure to the expert or consultant.
- 39. Absent timely objection, the expert or consultant shall be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order. Upon and pending resolution of a timely objection, disclosure to the expert or

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consultant shall not be made. If the Notifying Party desires to challenge to the Producing Party's written objection to the expert or consultant, the Notifying Party shall so inform the Producing Party in writing, within ten (10) days of receipt of the Producing Party's written objection, of its reasons for challenging the objection. The expert or consultant shall then be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order after seven (7) days from receipt of the Producing Party's timely challenge to the written objection to the expert or consultant, unless within that seven day period, the Producing Party seeks relief from the Court pursuant to the procedures for discovery disputes set forth in Section 9(o) of Case Management Order One, or the Parties stipulate to an agreement. Once a motion is filed, disclosure shall not occur until the issue is decided by the Court and, if the motion is denied, the appeal period from the Court order denying the motion has expired. In making such motion, it shall be the Producing Party's burden to demonstrate good cause for preventing such disclosure.

VII. Protection and Use of Confidential and Highly Confidential Information

- 40. Persons receiving or having knowledge of Confidential Information or Highly Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information or Highly Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential Information or Highly Confidential Information and will limit access to such material to those persons authorized by this Protective Order.
 - 41. Nothing herein shall restrict a person qualified to receive Confidential

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Information and Highly Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

- All persons qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or other work product derived from or containing Confidential Information or Highly Confidential Information in a manner to protect it from disclosure not in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein) are returned and surrendered pursuant to Paragraph 46. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.
- A3. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Confidential Information or Highly Confidential Information and, in the course thereof, relying upon such information, provided that in rendering such advice, Counsel

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shall not disclose any other Party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Protective Order.

- A4. Nothing contained in this Protective Order shall prejudice in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Protective Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, authentic, or admissible into evidence at any deposition, at trial, or in a hearing
- 45. Nothing contained in this Protective Order shall preclude any Party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any Party or the Court.
- 46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party.
- Information or Highly Confidential Information, it shall immediately (a) inform the Producing Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Confidential Information or Highly Confidential Information; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

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48. Unless otherwise agreed or ordered, this Protective Order shall remain in force after dismissal or entry of final judgment not subject to further appeal of this Litigation.

- 49. Within ninety (90) days after dismissal or entry of final judgment not subject to further appeal of this Litigation, or such other time as the Producing Party may agree in writing, the Receiving Party shall return all Confidential Information and Highly Confidential Information under this Protective Order unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return; or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Party elects to destroy the documents and certifies to the producing party that it has done so.
- Notwithstanding the above requirements to return or destroy documents, Plaintiffs' outside counsel and Defendants' outside counsel may retain (1) any materials required to be retained by law or ethical rules, (2) one copy of their work file and work product, and (3) one complete set of all documents filed with the Court including those filed under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Confidential or Highly Confidential Discovery Material shall continue to be protected under this Protective Order. An attorney may use his or her work product in subsequent litigation, provided that the attorney's use does not disclose or use Confidential Information or Highly Confidential Information.

¹ The parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information or Highly Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return emails (including attachments to e-mails) that may include Confidential Information or Highly Confidential Information, or Confidential Information or Highly Confidential Information contained in deposition transcripts or drafts or final expert reports.

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VIII. Changes in Designation of Information

If a Party through inadvertence produces any Confidential Information or 51. Highly Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Protective Order, the Producing Party may give written notice to the Receiving Party that the document or thing produced is deemed "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" and should be treated as such in accordance with the provisions of this Protective Order, and provide replacement media, images, and any associated production information to conform the document to the appropriate designation and facilitate use of the revised designation in the production. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information shall not be deemed a violation of this Protective Order. Any Producing Party may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" or withdraw a "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate description, along with the replacement media, images, and associated production information referenced above. Upon receipt of any redesignation and replacement image that designates material as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL", the Receiving Party shall (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this

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Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party's good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

A Receiving Party does not waive its right to challenge a confidentiality 52. designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of If a Receiving Party elects to press a challenge to a the chosen designation. confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party and the Receiving Party shall have seven (7) days from such notification to challenge the designation by commencing a discovery dispute under the procedures set forth in Section 9(o) of Case Management Order One. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the even that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media,

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images, and associated production information as provided above.

IX. Inadvertent Production of Documents

- 53. Non-Waiver of Privilege. The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing under Federal Rule of Evidence 502(b) and shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the "Disclosing Party"). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d).
- 54. Notice of Production of Privileged Information. If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

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Recall of Privileged Information. If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party's system:

- i. Locate each recalled document in the document review/production database and delete the record from the database;
- ii. If there is a native file link to the recalled document, remove the native file from the network path;
- iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;
- iv. Apply the same process to any additional copies of the document or database, where possible;
- v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as

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described herein:

vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to

vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

ensure that the recalled document will not be used; and

- 56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.
- 57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted ("Clawed-Back Information"), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information. Within 14 days after receiving the Disclosing Party's privilege log with respect to such Clawed-Back Information, a receiving party may notify the Disclosing Party in writing of an objection to a claim of privilege or work-product protection with respect to the Clawed-Back Information. Within 14 days of the receipt of such notification, the Disclosing Party

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and the objecting party shall meet and confer in an effort to resolve any disagreement concerning the Disclosing Party's privilege or work-product claim with respect to such Clawed-Back Information. The parties may stipulate to extend the time periods set forth in

this paragraph.

- 58. If, for any reason, the Disclosing Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Court pursuant to the procedures set forth in Case Management Order One. The Disclosing Party bears the burden of establishing the privileged or protected nature of any Privileged Information.
- 59. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.
- 60. In the event any prior order or agreement between the parties and/or between the parties and a non-party concerning the disclosure of privileged and/or work product protected materials conflicts with any of the provisions of this Order, the provisions of this Stipulated Order shall control.
- 61. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced.

X. Filing and Use at Trial of Protected Material

62. Only Confidential or Highly Confidential portions of relevant documents

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are subject to sealing. To the extent that a brief, memorandum, or pleading references any document designated as Confidential or Highly Confidential, then the brief, memorandum or pleading shall refer the Court to the particular exhibit filed under seal without disclosing the contents of any confidential information. If, however, the confidential information must be intertwined within the text of the document, a party may timely move the Court for leave to file both a redacted version for the public docket and an unredacted version for sealing.

- 63. Absent a Court-granted exception based upon extraordinary circumstances, any and all filings made under seal shall be submitted electronically and shall be linked to this Stipulated Protective Order or other relevant authorizing order. If both redacted and unredacted versions are being submitted for filing, each version shall be clearly named so there is no confusion as to why there are two entries on the docket for the same filing.
- 64. If the Court has granted an exception to electronic filing, a sealed filing shall be placed in a sealed envelope marked "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER." The sealed envelope shall display the case name and number, a designation as to what the document is, the name of the party on whose behalf it is submitted, and the name of the attorney who has filed the sealed document. A copy of this Stipulated Protective Order, or other relevant authorizing order, shall be included in the sealed envelope.
- 65. A Party that intends to present Confidential Information or Highly Confidential Information at a hearing shall bring that issue to the Court's and Parties' attention without disclosing the Confidential Information or Highly Confidential Information. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Confidential Information or Highly Confidential Information

at the hearing. The use of any Confidential Information or Highly Confidential Information at trial shall be governed by a separate stipulation and/or court order.

XI. Information or Highly Confidential Information Requested by Third Party; Procedure Following Request.

- Order (the "Receiver") is served with a subpoena, a request for information, or any other form of legal process that purports to compel disclosure of any Confidential Information or Highly Confidential Information covered by this Protective Order ("Request"), the Receiver must so notify the Designating Party, in writing, immediately and in no event more than five (5) court days after receiving the Request. Such notification must include a copy of the Request.
- 67. The Receiver also must immediately inform the party who made the Request ("Requesting Party") in writing that some or all the requested material is the subject of this Protective Order. In addition, the Receiver must deliver a copy of this Protective Order promptly to the Requesting Party.
- The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to protect its Confidential Information or Highly Confidential Information. The Designating Party shall bear the burden and the expense of seeking protection of its Confidential Information or Highly Confidential Information, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Litigation to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Receiver has in its possession, custody or control Confidential Information or Highly Confidential Information by the other Party in this Litigation.

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69. Materials that have been designated as Confidential or Highly Confidential Discovery Material shall not be provided or disclosed to any third party in response to a request under any public records act, or any similar federal, state or municipal law (collectively, the "Public Disclosure Laws"), and are exempt from disclosure pursuant to this Protective Order. If a Party to this Litigation receives such a request, it shall (i) provide a copy of this Protective Order to the Requesting Party and inform it that the requested materials are exempt from disclosure and that the Party is barred by this Protective Order from disclosing them, and (ii) promptly inform the Designating Party that has produced the requested material that the request has been made, identifying the name of the Requesting Party and the particular materials sought. If the Designating Party seeks a protective order, the Receiving Party shall not disclose such material until the Court has ruled on the request for a protective order. The restrictions in this paragraph shall not apply to materials that (i) the Designating Party expressly consents in writing to disclosure; or (ii) this Court has determined by court order to have been improperly designated as Confidential or Highly Confidential Discovery Material. The provisions of this section shall apply to any entity in receipt of Confidential or Highly Confidential Discovery Material governed by this Protective Order. Nothing in this Protective Order shall be deemed to (1) foreclose any Party from arguing that Discovery Material is not a public record for purposes of the Public Disclosure Laws; (2) prevent any Party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any arguments that a Party may make as to why Discovery Material is exempt from disclosure.

XII.HIPAA-Protected Information

12.

- 70. General. Discovery in this Litigation may involve production of "Protected Health Information" as that term is defined and set forth in 45 C.F.R. § 160.103, for which special protection from public disclosure and from any purpose other than prosecuting this Action is warranted
- 71. "Protected Health Information" shall encompass information within the scope and definition set forth in 45 C.F.R. § 160.103 that is provided to the Parties by a covered entity as defined by 45 C.F.R. § 160.103 ("Covered Entities") or by a business associate of a Covered Entity as defined by 45 C.F.R. § 160.103 ("Business Associate") in the course of the Litigation, as well as information covered by the privacy laws of any individual states, as applicable.
- 72. Any Party who produces Protected Health Information in this Litigation shall designate such discovery material "Confidential Protected Health Information" in accordance with the provisions of this Protective Order.
- T3. Unless otherwise agreed between counsel for the Parties, the designation of discovery material as "Confidential Protected Health Information" shall be made at the following times: (a) for documents or things at the time of the production of the documents or things; (b) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and other documents, at the time of the service or filing, whichever occurs first; (c) for testimony, at the time such testimony is given by a statement designating the testimony as "Confidential Protected Health Information" made on the record or within thirty (30) days after receipt of the transcript of the deposition. The designation of discovery material as "Confidential Protected Health

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Information" shall be made in the following manner: (a) or documents, by placing the notation "Confidential Protected Health Information" or similar legend on each page of such document; (b) for tangible things, by placing the notation "Confidential Protected Health Information" on the object or container thereof or if impracticable, as otherwise agreed by the parties; (c) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and any other documents containing Protected Health Information, by placing the notation "Confidential Protected Health Information" both on the face of such document and on any particular designated pages of such document; and (d) for testimony, by orally designating such testimony as being "Confidential Protected Health Information" at the time the testimony is given or by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days after receipt of the certified transcript of the deposition.

Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities and their Business Associates (as defined in 45 C.F.R. § 160.103), or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to the Action to those persons and for such purposes as designated in herein. Further, all Parties that are entities subject to state privacy law requirements, or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to this Action to those persons and for such purposes as designated in herein. The Court has determined that disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more parties to the proceedings.

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75. The Parties shall not use or disclose Protected Health Information for any

purpose other than the Litigation, including any appeals. The Parties may, inter alia,

disclose Protected Health Information to (a) counsel for the Parties and employees of

counsel who have responsibility for the Litigation; (b) the Court and its personnel; (c) Court

reporters; (d) experts and consultants; and (e) other entities or persons involved in the

Litigation.

76. Within sixty days after dismissal or entry of final judgment not subject to

further appeal, the Parties, their counsel, and any person or entity in possession of

Protected Health Information received pursuant to this Order shall destroy or return to the

Covered Entity or Business Associate such Protected Health Information.

77. Nothing in this Order authorizes the parties to obtain Protected Health

Information through means other than formal discovery requests, subpoenas, depositions,

pursuant to a patient authorization, or any other lawful process.

XIII. Information Subject to Existing Obligation of Confidentiality Independent of

this Protective Order.

In the event that a Party is required by a valid discovery request to 78.

produce any information held by it subject to an obligation of confidentiality in favor of a

third party, the Party shall, promptly upon recognizing that such third party's rights are

implicated, provide the third party with a copy of this Protective Order and (i) inform the

third party in writing of the Party's obligation to produce such information in connection

with this Litigation and of its intention to do so, subject to the protections of this Protective

Order; (ii) inform the third party in writing of the third party's right within fourteen (14) days

to seek further protection or other relief from the Court if, in good faith, it believes such

information to be confidential under the said obligation and either objects to the Party's

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production of such information or regards the provisions of this Protective Order to be inadequate; and (iii) seek the third party's consent to such disclosure if that third party does not plan to object. Thereafter, the Party shall refrain from producing such information for a period of fourteen (14) days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief, the Party shall promptly produce the information in question subject to the protections of this Protective Order, or alternatively, shall promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

XIV. Miscellaneous Provisions

- 79. Nothing in this Order or any action or agreement of a party under this Order limits the Court's power to make any orders that may be appropriate with respect to the use and disclosure of any documents produced or use in discovery or at trial.
- 80. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.
- 81. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the Producing Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Producing Party shall do so, the respondent person, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the Producing Party possesses an adequate remedy at law.
- 82. This Protective Order shall not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery

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Material called for, and access to such Discovery Material shall be only as provided for by

separate agreement of the Parties or by the Court.

83. This Protective Order may be amended without leave of the Court by

agreement of Outside Counsel for the Parties in the form of a written stipulation filed with

the Court. The Protective Order shall continue in force until amended or superseded by

express order of the Court, and shall survive and remain in effect after the termination of

this Litigation.

84. Notwithstanding any other provision in the Order, nothing in this

Protective Order shall affect or modify Defendants' ability to review Plaintiffs' information

and report such information to any applicable regulatory agencies.

85. This Order is entered based on the representations and agreements of

the parties and for the purpose of facilitating discovery. Nothing herein shall be construed

or presented as a judicial determination that any documents or information designated as

Confidential or Highly Confidential by counsel or the parties is subject to protection under

Rule 26(c) of the Federal Rules of Civil Procedure or otherwise until such time as the

Court may rule on a specific document or issue.

IT IS SO ORDERED.

Dated: 5/15/18 /s/Dan Aaron Polster

Honorable Dan Aaron Polster United States District Judge

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IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	Case No.: 1:17-md-2804-DAP
This document relates to:	Honorable Dan Aaron Polster
All Cases	

EXHIBIT A TO CASE MANAGEMENT ORDER NO. ______ ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order (CMO No. __) that was issued by the United States District Court for the Northern District of Ohio on_____, 2018 in *In re: National Prescription Opiate Litigation* (the "Protective Order").

I agree to comply with and to be bound by all the terms of the Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to the Protective Order to any person or entity except in strict compliance with the provisions of the Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of Ohio for the purposes of enforcing terms of the Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

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Date:
City and State where sworn and signed:
Printed Name:
rinted Name.
Signature: